HIT Standards Committee
Draft Transcript
October 27, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody, and welcome to the 18th meeting of the HIT Standards Committee. Just a reminder, this is a federal advisory committee. There will be opportunity at the end of the meeting for the public to make comments. A reminder also to the members of the committee to please identify yourselves when speaking.

Let's go around the table now and introduce ourselves beginning on my left with Walter Suarez.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Walter Suarez with Kaiser Permanente.

John Klimek – NCPDP – VP Industry Information Technology
John Klimek, NCPDP.

John Halamka – Harvard Medical School – Chief Information Officer
John Halamka, Harvard Medical School and Beth Israel Deaconess.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Jamie Ferguson, Kaiser Permanente.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Liz Johnson, Tenent Healthcare.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Chris Chute, Mayo Clinic.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
John Derr, Golden Living.

Kevin Hutchinson – Prematics, Inc. – CEO
Kevin Hutchinson, Prematics.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
Anne Castro, BlueCross BlueShield of South Carolina.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Jim Walker, Geisinger Health System.

Judy Sparrow – Office of the National Coordinator – Executive Director
We do have a number of members on the telephone. Wes Rishel, are you there?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Wes Rishel, Gartner.

Judy Sparrow – Office of the National Coordinator – Executive Director
Dave McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
David McCallie, Cerner.

Judy Sparrow – Office of the National Coordinator – Executive Director
Any other members on the telephone?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes, Carol Diamond, Markle.

Judy Sparrow – Office of the National Coordinator – Executive Director
With that, I'll turn it over to Dr. Halamka.

John Halamka – Harvard Medical School – Chief Information Officer
Good morning, everybody. For those of us who are in Washington, this is the proud, the few, the stalwart who were willing to deal with 40 mile an hour winds, and when rain hits Washington, traffic does slow a bit. So thanks, everybody, for being here. I know Dixie will be a few minutes late.

Today is our last in-person meeting for the year. The November and December meetings will be virtual, and that was because of their proximity to Thanksgiving and the holidays, so I think that will work out well. Today's meeting, an important meeting, will be discussing three major items. Paul Tang and George Hripcsak will be talking about meaningful use stage two and three from a philosophical standpoint. Recognize that they had a meeting on the 20th, and it is still, I would say, a bit early to define precisely the transactions that will flow and, therefore, the standards, content, vocabulary, and transmission to be required. But what we hope is today we can get a sense of philosophically where they are going, and that will give us a sense of where we need to be. It's again one of these skating where the puck is going to be kind of exercises, as we did before.

One of the things I've heard David Blumenthal say several times is that they're going to be very careful about stage two and three, and really won't finalize them until after we look at the success of stage one. One hopes that we will have generous time as opposed to, in previous work, we had to move at extraordinarily accelerated rates, so today is really a kickoff meeting from a meaningful use perspective, and tee up some of the major topics, I think, rather than specific standards we'll be working on over the next couple of months.

Then we're going to hear from Doug and Arien on two important topics. Doug will talk about progress on the S&I framework because, remember, he has these ten RFPs, and it's his challenge to knit together all these various contractors and the process from use case definition now to creating running code, reference implementation, and tests. And so he will talk to us about how that kickoff meeting and planning has gone and what they think the work of the next year will be. You'll see, it's really more of a process layout.

One of the things that I think is interesting in discussions that I've had with many people, there was some trepidation about the word NIEM, as in NIEM implied a set of activities that were really focused around homeland security and certain kinds of standards constructs that were actually specific to that activity. I think what you'll see in Doug's presentation is he is now more focused on processes than nomenclature. That is, you're not going to see, at least in the slides he has today, the word NIEM appearing a lot. It's just here are the things we are going to do, and here is who is going to do them.

Of course, this group is going to provide some governance oversights to that. I think that's really a good idea because I think NIEM has been a valuable learning experience for the country, but we want to suggest what are those processes we inherit from it, as opposed to what are the very specific standards

constructs we inherit from it because you've probably heard Doug say multiple times, it was never the intent of suggesting that somehow healthcare and homeland security would either be connected to each other using the same standards. It was really more of a learn from the process. I think that's good in the way you'll see his slides presented.

Arien, today, a really important milestone for NHIN Direct. NHIN Direct has been a project rather than a product, and we are going to hear about what have they done to achieve consensus. What has been their model of governance? Where have they gone over the last year of work? Now it's funny because when NHIN Direct was first put together, my sense was there were a number of folks who said, you know, what we need is simple and easy. By the way, if we look to Google, and we look to Amazon and Facebook, they're all using these restful transactions. It's just HTTP from point-to-point, very, very simple.

What Arien did was he put 100 experts in the room, and they all thought about the use cases and the security and everything that had to be done, and I think you'll see in his presentation today, they ended up with all the standards except REST, so that you'll see from him that they have really two tracks, which are very valid. XDR, the SOAP transactions that HITSP had worked on, and SMTP with TLS secure e-mail, which certainly could be simple, but there are aspects for any of us who have implemented secure e-mail around security that aren't always simple like where do the certificates lie, and who do you trust, and how does all that work? It would be fascinating, as we hear from him, what lessons we can learn from bringing 100 people together in a governance model, and how do you achieve consensus or something close to it. What are the actual running code implementations that NHIN Direct will deliver?

Now one of the things that's kind of interesting, just in the environment, is SureScripts announced on Monday that they will be making the NHIN Direct exchange model available over the SureScripts network, which already connects so many hundred thousand physicians in this country. So it'll be really an interesting organic experiment to go from what we will hear today as a set of running code to what is now one company and could be other companies actually implementing this running code to start exchanging data. I think, in the next year, we'll certainly learn quite a lot, as transactions begin to flow. In a sense, today, Arien is looking for our comments and our view of their work. Certainly be open, honest, ask any question you wish because I think NHIN Direct was an experiment and a new way to approach making and there are positives and negatives, so let's examine that.

Then we will hear from Judy Murphy and Liz Johnson on the implementation workgroup, and Jamie on the vocabulary taskforce specifically addressing such issues as intellectual property and where do we go to advance that particular effort. That is the agenda. In terms of timing, because we are a bit of a smaller group today, and because the agenda, I think, probably from Judy, Liz, and Jamie, will be slightly compressed, we may be completed by 12:30 or so. I only say that to the people in the room because thunderstorms approaching the East Coast are supposed to get quite severe between 2:30 and 5:30, so we're going to try to get you home before the storms hit.

With that, one administrative item, remember, again, November and December will be virtual, so no need to schedule travel or hotel. We do have a set of minutes to approve today. Jamie Ferguson already made amendments to those minutes, which was incorporated in this document. Were there any other comments or edits to the minutes? Okay. Well, none being heard, the minutes are approved. Do we have Paul Tang?

Judy Sparrow – Office of the National Coordinator – Executive Director
Paul, are you on the line? I know, George Hripcsak, you're there, correct?

George Hripcsak - Dept. of Biomedical Informatics Columbia University – Chair
I am here, but we do need Paul.

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes, I know. So maybe what we'll ask, John, is to have Jamie go.

John Halamka – Harvard Medical School – Chief Information Officer
Jamie, if you could kick us off, and then Paul Tang will join us.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Sure. I'd be happy to. Thank you. I'm going to give a very brief update on the status and next steps for the vocabulary taskforce. We are working towards a set of recommendations to bring forward to the committee, as we discussed previously, primarily around how to manage intellectual property issues for meaningful use related to the vocabularies, how to make those issues, if not disappear, have them easily managed by eligible professionals and hospitals and any other organizations that are the intended recipients of the meaningful use incentives. In general, what we're working on right now is a couple of activities so that we can better understand the current landscape of who pays for what, how intellectual property issues are managed by the same entities for other purposes, and then what's different about meaningful use so that we can come to a set of recommendations that specifically relate to the needs related to meaningful use and especially around the content sets for performance measures and quality measures related to meaningful use.

What we have underway right now is an analysis that's being led by the National Library of Medicine, by Betsy Humphreys, of essentially who pays for what standards today. What are the models that are being used? This is, again, related to vocabulary, but it also includes the use of vocabulary and the messaging standards such as those for the administrative simplification transactions, which certainly contain some vocabulary content sets. So that analysis is underway. We have a first draft. It's not ready for even for full discussion by the committee yet.

The other activity that's underway is being led by Floyd Eisenberg, and that is gaining better understanding of the coordination of measure sets. So part of our previous testimony that we talked about earlier was the need for some central coordination of the standards that are used in the content sets across different measures that are developed by different measure developers so that we're sure that terms have the same meaning wherever they're used. Also, we had the idea that there would be a primary organizing principle for the development of the content sets and the measures by domain. Some examples of that would be the current domain management in PHIN VADS or bridge, and so we wanted to understand again the landscape of those domain management schemes that currently exist for the same vocabularies that are used in meaningful use so that we can then analyze what's different about the needs for meaningful use. Hopefully we'll be able to bring forward recommendations in one of the next upcoming meetings. We're just still working on that.

John Halamka – Harvard Medical School – Chief Information Officer
Before the meeting, Jamie and I were talking about some of these issues in detail, and let me give you some sense of how it is that this intellectual property issue can be a barrier. Anne, you're a payer. I'm a provider. I buy a license to intellectual property and generate data. I am the data generator. I then send you the resultant document or structured data, and you might aggregate and report back on that, pay for performance measures or maybe something even related to generating reimbursement to me.

Due you also have to buy a license for the intellectual property, even though I already paid for it, and I was the data generator? This is a sort of fascinating question. And so as you go through this work, it may turn out we can clarify this for the industry. That is to say, if you too are a data generator, yes. Or if you need such a vast array of the code sets because of some activity, you could see that, but if it's truly you are a business associate of mine processing data I generated on my behalf, the answer is probably no. That's an issue to be worked through.

Another issue is, for example, in meaningful use, we have RxNorm. RxNorm requires there's a set of mapped vocabularies underneath it for multiple commercial products and intellectual property that's open source. But if you actually study RxNorm, it isn't a complete set of data. That is, the commercial entities

have not contributed everything about their particular proprietary code sets. If in fact meaningful use requires that you fully embrace RxNorm, but you can't fully embrace RxNorm because the code sets are incomplete, should the commercial entities, without compromising intellectual property value, at least provide to the open source community a map of all of their proprietary code sets to the RxNorm or other standards that might be adopted by this committee because this is a challenge that Floyd has is that when Floyd says, I'm going to tell you SNOMED CT or RxNorm, but you happen to use internally a proprietary code set or ICD-9, you have to do the mapping yourself. That's going to be a challenge for everyone.

As I look at the reports you guys are going to give on the implementation workgroup, there are certainly measure sets, performance measures, as part of that discussion. You would think that ideally we would get to a point. Nirvana would look like one Web site where I could download all of the vocabularies necessary for the implementation of meaningful use and all cross maps necessary to go from proprietary to required code sets and clarity as to who needs to pay for what. Of course, the last meeting, we discussed multiple models for doing that where the administratively simple one would be the federal government just simply agreed to license intellectual property on behalf of the implementer community. Any comments you'd make?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. The only addition I'd make is just to the point you just made, to amplify on that from our previous, our discussion in the last meeting, is we did determine that we wanted to explore two alternative models for making these issues simple for implementers. One is some form or perhaps multiple forms of a national license paid by the government with potentially some cost recovery scheme on perhaps a fee, something of that nature for eligible professionals, hospitals, and other organizations in meaningful use. The second being the administrative model that you just mentioned where essentially an officer agency or contractor of the federal government would administer these licensing fees on behalf of the users of the intellectual property.

The idea is, and what we heard very clearly from our testimony of our hearings in September is that although free is always better, and everybody wants things to be completely free, generally we heard that providers don't mind paying. They're used to paying for standards. But they want to have one check go to one place and make it simple for us so that they don't have to track their use of the different aspects of different intellectual property and figure out who to pay how much for what. One check to one place would make it simple for the eligible professionals and hospitals.

John Halamka – Harvard Medical School – Chief Information Officer
The example I would give, each of the state's regional extension centers probably has a little bit of a different business model, but in Massachusetts, the clinicians are asked to pay a yearly membership fee to the REC for the services they derive. Of course, the benefits are going to be very significant. As they achieve meaningful use, they get $4,500 for doing so, and they're quite fine as long as there are benefits to pay some de minimum membership fees.

You could imagine a $100 vocabulary fee charged to every provider in America per year for which the benefits would be stimulus dollars and increased Medicare payments. Why not? It's just the administration of the collection of such fee and the tallying of who paid and who didn't that could get nightmarish. My own experience running organizations is sometimes charge backs are more expensive to administer than the money you collect. That's the challenge.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
That was exactly our discussion last time was that that cost analysis needs to be done to make that determination.

John Halamka – Harvard Medical School – Chief Information Officer
Any questions for Jamie?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Did you consider taking the $100 or whatever it is out of the first reimbursement check?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think the mechanism for that would have to be up to ONC, but that's certainly potentially a viable option.

John Halamka – Harvard Medical School – Chief Information Officer
Comments? Jamie, you're not controversial this morning. Maybe it's because you went first.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes.

John Halamka – Harvard Medical School – Chief Information Officer
Do we have Paul Tang at this point?

Judy Sparrow – Office of the National Coordinator – Executive Director
Paul, are you there? I've e-mailed him.

George Hripcsak - Dept. of Biomedical Informatics Columbia University – Chair
Yes. I messaged him. We'll see what happens.

John Halamka – Harvard Medical School – Chief Information Officer
We could move on to Liz and Judy.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Judy is not able to join us this morning. This is Liz Johnson, and I'll be reporting back from the implementation workgroup. If we'll go to those slides, please, the first thing I want to point out to you is we have a couple of new members. Tim Morris, thank you. Dixie has joined us from Emery University. He really represents a great deal of information around the public sector. Then also Amira Choi has joined us from ONC formally to be our liaison, so those are two persons that I think will be very instrumental in our process going forward.

I'll remind you again of our broad course. I think John Halamka was already referring to. We really are about taking what's going on with implementation, gaining from those experiences, and then beginning to formulate ways to respond in a more proactive way to what our constituents need. We've had another meeting, and we'll report back on that, and have two coming up. Again, we'll continue to report back on a monthly basis.

We want to put forward to the committee this morning a couple of activities that we'd like to suggest to you. The first one is, we'd like to have a panel hearing in January of 2011, and the purpose of the meeting is to really discover real life experiences from people working with meaningful use, as they go through the implementation process. We began to sort of lay out not only the objectives of this, but also the strategy in which we would move forward to select the panels. So we really want to go out to the eligible providers and ask them, how are your meaningful use implementation experiences going? What about it is coming together and being fairly obvious in terms of what you need to do to get ready? Then what kinds of things have you run into in terms of barriers that we can assist you, so you can be successful?

We also want to obtain information from the certifying bodies and what kind of experiences they're having around certification, and then obviously we want to look at the RECs and the state HIEs and so on. So we're trying to cover the environment in terms of those that are contributing to our ability to meet implementation requirements. That's a tentative activity that we have in front of us.

There's also another one. There is an adoption workgroup within the policy committee, and we're having discussions with them, along with Doug Fridsma, to determine are there synergies that we can obtain by either bringing those two groups together or certainly aligning their activities, doing the panel discussions together and that sort of thing. Those initial discussions have taken place, and additional discussions are already planned for the immediate future. When we get to the November meeting, we'll be reporting back to you on where we have landed on that, either again, certainly we'll synergize our activities and maybe combine the two committees.

If we go back to the panel discussion and talk about some proposed panels that we have and would like to seek input from the standards committee about the type of panels. The first one we want to look at is the RECs. We want, first of all, to hear from the ONC on what the intent was, what they determined the RECs would be providing to our constituents. Then we really want to get the information from the RECs themselves.

There are two models of RECs that are currently out there. One is a franchise model, and one is from the QIOs. We'd like to hear from them how are they progressing, how are they interacting with their constituents? What kind of lessons can they not only share with each other, but share back with us? Then, obviously, very important to us, we want the user perspective because we're hearing a variety of feedbacks from those that are using the RECs. Is it successful? How is it helpful? How can we improve it? That would be our first panel.

Then we want to move into the certification experience. We really want to look at it from three perspectives. First of all, obviously from CCHIT and some of the other certified bodies that are now doing accreditations for or certifications for us. We want to do self-certification. John and I were talking prior to the meeting. There are four organizations that are currently in the pilot for that, John's organizations being one of those. We want to hear what's being required, what does that look like, how is that process working.

Then, from the vendor perspective, we obviously have a large number of EHR vendors. Are they getting to the certification process? We're beginning to see preliminary results of those that are getting at least preliminary certifications. How is that working? What else needs to be done?

The third part of the panel would include the early adopters. We know that there are persons who are already lining up to get meaningful use certification during this current fiscal year. We want to hear from the whole gamut of those persons, both small and large practices, and small and large … and providers. So again, we would go across the nation and seek those that are actually planning to get their meaningful use certification during this fiscal year.

Then we want to look at the criteria itself, the meaningful use criteria. We know that we have stage one, and we are beginning to gain some significant understanding about that. In a little while, we'll hear from Paul about stage two and where we'll be moving to. We want to combine both sets of knowledge and determine, again, are we headed in the right direction? There are things that we can advise, those that are adopting early, on meaningful use, and help them set that pathway for the future.

Then, finally, we want to look at the health information exchange arena that is becoming clear, as we move forward in this process, that we're going to need to be absolutely sure that we are … we need to look at both the public and private sector alternatives for the health information exchange, and how those are beginning to lay out in the country. We're seeing activity at the stage level. We're seeing that to be at the national level. Certainly the private vendors are bringing those exchanges forward.

Those are the current recommendations around the panel and the types of persons that we would engage in the process. We would do that. In January, we are thinking probably a day and a half. We don't think we can collect this type of information and do these hearings adequately in just a day. Certainly all of you will be invited to participate.

As we go forward, and we plan for what's coming next, we need to more clearly define the January 2011 hearing, soliciting again your input. We need to develop the questions and provide testimony guidance so that we have a clear objective in mind as those testifiers come forward, and we have the end in mind and are clear of what we plan to obtain from those hearings. Obviously we just need to get the logistics out there. Judy is working with us. We'll get dates and that sort of thing.

I also had a request from our workgroup that we began to get more informational updates because we have a mix of people in our group. Some participate in these workgroups, and some do not. They would like more information from the ONC on all the activities, so we've asked Doug and others to come and do educational sessions for us. Then, finally, we talked about earlier, we need to develop the plan to either merge or certainly work in a synergistic way with the adoption group as a policy committee.

Those are the things that we worked on last time, and Anne is here and others. Please feel free to add to the review of what we accomplished during that last meeting, and then certainly take input from the group.

John Halamka – Harvard Medical School – Chief Information Officer
Just to comment on certification experiences, in chatting with some of the certification entities, I've heard such things as EHR vendors have had to create the wrong standards in their EHR for syndromic surveillance because we all know that the wrong implementation guide was actually placed into the regulations, so they've actually, for certification, created software that can't possibly work. Now obviously this is something that is a short-term problem. Doug, presumably, when he arrives, can describe what the ONC plan is.

I think there's been some debate inside ONC how to correct this problem, such as issuing an interim final rule suggesting that the final rule has a mistake in it, and you should ignore it. But there is obviously, from a legal perspective, a set of constraints on how one undoes a final rule that publishes the incorrect information. But in the meantime, the certification entities really have no choice, but to certify to what is in the final rule. Now is there a representative from NIST here today?

Judy Sparrow – Office of the National Coordinator – Executive Director
Kamie may be. Kamie, are you on the phone?

Kamie Roberts – NIST – IT Lab Grant Program Manager
Yes, I'm here.

John Halamka – Harvard Medical School – Chief Information Officer
Kamie, could you clarify one thing for me? What I'd also heard on certification experiences is that although I believe the standards committee said NCPDP 8.x or 10.x, we did not specify an XML or EDI form, and then I had heard that some vendors, when using some NIST test scripts, were told we don't actually support the XML form on our test script. Therefore, you must certify to the EDI form. Do you know anything about that?

Kamie Roberts – NIST – IT Lab Grant Program Manager
No, I'm not sure about that, but I'll check on it and get back to you.

John Halamka – Harvard Medical School – Chief Information Officer
I guess not. Kamie, can you hear me?

Kamie Roberts – NIST – IT Lab Grant Program Manager
Yes, can you hear me?

John Halamka – Harvard Medical School – Chief Information Officer

Sorry, yes. You cut out there.

Kamie Roberts – NIST – IT Lab Grant Program Manager
I'm sorry. I don't have an immediate answer to that, but I'll check on it and get back to you today during the meeting.

John Halamka – Harvard Medical School – Chief Information Officer
Great, because really the challenge was that if there are allowable forms because we weren't specific, that NIST would then test for both forms, and either of those forms would suffice. So I had heard that in the 11th hour, you had totally compliant 8.x or 10.x transactions that couldn't be certified because NIST didn't have the test script for the particular implementation. So if you could clarify EDI versus XML form of NCPDP, that would be great.

Kamie Roberts – NIST – IT Lab Grant Program Manager
I'll do that.

John Halamka – Harvard Medical School – Chief Information Officer
But these are the kinds of issues. If vendors create products that are interoperable, but then for reasons of the regulation or the reason of test scripts, have a challenge in the actual implementation, that's the kind of thing that we want to bring forward and correct.

Kamie Roberts – NIST – IT Lab Grant Program Manager
Absolutely.

John Halamka – Harvard Medical School – Chief Information Officer
Walter, a comment?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes. About the hearing, I have a couple of comments. It seems like a perfect time to get some baseline information on several of these programs. One question is about three and four. Number three is the early adopters of meaningful use. Number four is the meaningful use criteria itself.

I'm just wondering what would be the objective, particularly with number four, is it to understand what are some of the questions that people have about the meaningful use criteria, and is that sort of combined with number three? Yes, thanks. In the number three, it looks like you're bringing testifiers that are early adopters of meaningful use, and will probably express perspectives or provide perspectives on the criteria, I suppose. In number four, what's your goal there? Is it …?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
When we made the differentiation, we were talking about meaningful use seekers, so to speak, in 2011 being a fairly small group coming forward. But there are a number of people that are sitting on that cusp that would like further clarification and to bring forward questions, and those are the persons that would be in the fourth panel, so really getting clarification. I think, again, as we recognize as the meaningful use workgroup that Paul is leading is beginning to formulate stage two, it's another opportunity for us, as those early sort of notions are coming out about what is expected to give us feedback for that as well.

John Halamka – Harvard Medical School – Chief Information Officer
Walter, let me give you an example of a challenge that I face. It turns out, the way that a numerator and denominator may be defined with regard to specific quality measures may be challenging for me to actually accomplish. Many hospitals have sophisticated medication management workflows. When we think about it, a doctor places and order, and there's a time/date stamp on the order for the med. A pharmacy dispenses the med. You might have a device like a PIXUS device or an omni cell where you can actually physically record the administrator of the med taking it out.

You may or may not have an EMAR, and electronic medication administration system. At the moment the med touches your tongue, I'm scanning your wristband and recording. If the measure says, did the patient receive the medication within 20 minutes of arriving in the emergency department, it was ordered. It was dispensed. Did it touch their tongue? I'm not sure. These are the kinds of realities we'll have to deal with.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes. Exactly. I think, I mean, to be fair probably with the complexity of the many questions, I think that probably by itself could take probably a whole day of hearings. One suggestion perhaps about the process is because if you invite four testifiers, which probably as much as you could fit into one of these panels, you would get four perspectives. But it might be better, or another way to get more feedback, if you open up and use, for example, some of the federal blog opportunities for people to submit questions and to kind of get a lot of other perspectives to be brought to the panel or the session, focusing on meaningful use, and try to summarize. We've got 100 questions. I don't' know. But if these were the kinds of topics that were covered so that, at the end, you get a much larger crosscut of the various questions and perspectives, there are probably a lot of questions around those. That's just one suggestion ….

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, that's terrific input. In fact, we had suggested to Doug, and it's not reflected here, but we had asked him about sort of relaunching a multimedia communication tool for the public to answer those very kinds of questions. He felt like that was certainly something that the ONC could and would do. One of the things that we … as part of our charge is to bring back to this committee because we had said there are—Cris helped us start a blog, but there are many ways that people could be communicating with us real time about the sort of things that are defined. I think that's a terrific idea.

John Halamka – Harvard Medical School – Chief Information Officer
Great.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Then my last comment is on the number five, the health information exchange. I think nowadays basically every state has identified and designated a health information or actually a health IT state coordinator, and I think it will be, I mean, they are probably some of the individuals that are closer to the reality of what's happening at the ground level with respect to HIEs. So my suggestion is to consider including their perspective in bringing in a group of state HIE coordinators to discuss and to present about the HIE efforts in their respective states. And there are states at different levels of development, so that's just another suggestion.

John Halamka – Harvard Medical School – Chief Information Officer
Great. Kevin?

Kevin Hutchinson – Prematics, Inc. – CEO
My comment is on the RECs themselves, and this has come up. Obviously we've seen this throughout the blogs and other areas and other meetings where ONC is well aware that there's a serious concern about some of the business models of the RECs in endorsing particular vendor solutions or proprietary approaches to how they're going to fund themselves, which is not the original intent. It's to provide support to the practices for the solutions that they implement. But with respect to the panel that we want to have in the RECs, we want to make it clear it's not our intent to get into the business model issues of the RECs. It's more of how they're applying and supporting the effort to get to meaningful use. But I know that it's going to be addressed in a different setting other than these panels. But I can see, because it's becoming such a hot topic that by the time we get to that panel, that might be an area of focus, but we're really going to focus on the standards.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
The way they're meeting. Correct.

Kevin Hutchinson – Prematics, Inc. – CEO
Yes. That's good.

John Halamka – Harvard Medical School – Chief Information Officer
Kevin, your point is very well taken. Beyond the scope of this committee, the business model of the REC is a fascinating discussion. On average, it costs me about $30,000 to bring a clinician to meaningful use in the community when I'm going out to a small doctor's office that has no automation. If there is a $5,000 benefit, I risk $30,000 to get $5,000. I'm not sure that investment is really attractive. This is, I'm sure, a debate for another panel. Certainly there will be implementation issues around that. Jim, you were next.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Two things. One is a methodology suggestion. When you do the testimony, I thought Walter's suggestion was great. One powerful way to do that is to say, okay, this testimony is a small population, but they will raise issues that we want to know how prevalent are they in the larger population. So, if it were possible to follow the testimony with a questionnaire that went out to what—if we could identify and reach that larger population, I think that might give us what we often don't get, which is how prevalent is it rather than how loud is the feedback.

The second on the self-certification perspective, I'm going to make some suggestions, which you'll probably need to correct, Liz, and then a comment. I'm assuming that the four have fairly robust health IT functions, and I also believe—I think I know—that there's a larger population out there who have generally less robust health IT functions who think that they might be subject to individual certification, but don't know. If there were any way to capture that experience, I think that is probably important for your committee and our committee to understand if we can.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes. I think that's a great point. In fact, one of the things that we're doing is we have two … we're going to have to certify. One is proprietary, much different from what you're going through, John, at Beth Israel. But it's still, we're sort of digging our way through how do you actually do that? What you're saying is we should have a balance between the pilots and that sort of effort. That's a very good suggestion.

John Halamka – Harvard Medical School – Chief Information Officer
Anne?

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
I just wanted to add on the HIEs and the REC centers, real important, before we even get to the testimony and framing it up, is the education we're going to get from ONC because there is such as big picture, and there was an original charge for each of these pieces, and it could get easy to throw a solution at a problem, and it's already designated in one space. We want to make sure we understand where those spaces are, so I think it's very important. You'll see that through our feedback what that education brings to the table, so it helps us with the testimony, driving the testimony.

John Halamka – Harvard Medical School – Chief Information Officer
Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Liz, I want to go back to the point that Jim makes. I think it's really good. I could only attend part of the meeting that we had on the 7th. I apologize, but I know in one of our earlier meetings, we talked about the idea of trying to get data around progress towards implementation. The survey data was important, but when you talked about the briefings from ONC staff, I think the thing we talked about was without

inventing a new, expensive, difficult process, how do we know what the report card looks like? I don't know if we still have some energy behind that idea, but I thought it was a really good one and would love to see us do that.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
The report card that Chris is referring to is we had asked the ONC to be able to provide that to this committee and provide probably frankly where everybody is in terms of certification, in terms of applying for meaningful use attestation and then actually attaining it. So they have said that that will be coming forward. We ought to ask them to bring forward a template, Judy, so that we could actually see what that might be like. Then we would know it was in progress.

John Halamka – Harvard Medical School – Chief Information Officer
One of the things that's interesting about a report card, certainly you could guess such a report says were these standards successfully implemented, but does the implementation of standards guarantee interoperability? Sometimes people say, but wait a minute. It's a certified system. Of course it should talk to every other certified system. Maybe by 2015, right? We will just need to keep that in mind as well because a certified system, I mean, today the standards and the content are probably pretty well specified, although there is some optionality that will provide a lack of interoperability. But transmission has some basic security standards, but not a lot of detail that will insure one system can connect to another, and we should be sensitive about those gaps. Of course ….

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
John?

John Halamka – Harvard Medical School – Chief Information Officer
Yes. Wes, we were feeling so lonely.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes. Right. You managed to wake me up here. As you know, I have been … I've been trying to find that point where different organizations stop passing the buck down the chain to get to interoperability for 20 years now, and I think we really need to look at the few successful implementations of that and compare that to our model before we say that there's a time when we can get there. It might be a matter for the implementation committee to take up at some point. I know there have been hearings on it. I don't think we've blown the depths of it though.

John Halamka – Harvard Medical School – Chief Information Officer
Any other comments? Keith Boone has just e-mailed me that in fact an IFR was published by ONC identifying the issue with syndromic surveillance 14 days ago, so I hadn't yet seen that. So they're well on their way to correcting that problem. Very good. I think we are ready then to move on to the meaningful use workgroup update. Is Paul Tang on the line?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Yes, I am.

John Halamka – Harvard Medical School – Chief Information Officer
Good morning, Paul, and thanks so much. I presume you're in California.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
I am.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

I'm sitting in my car in California actually.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks so much for getting up so early. I introduced your presentation today by suggesting that you and George would go through a philosophical update on where you are, where your thinking is headed on stage two and stage three, recognizing that, at the moment, you may not be ready to specifically charge us with individual transactions for which the standards committee would begin work, but you would at least give us a general direction of where you're headed.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Correct. That's a good introduction, John. Are the slides up?

John Halamka – Harvard Medical School – Chief Information Officer
Yes, the slides are up.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
This is a presentation that George and I are going to make and update you on really where we're thinking from a sort of philosophical approach, which we just presented last week to the policy committee and got some feedback, and so we're charged to go back and work on the criteria based on the feedback and sort of the direction that we were heading. And I will cover that in this presentation this brief presentation. This is just to refresh your memory on the terms of the workgroup membership. George and I lead this group. It's a nice, diverse group, a lot of thoughtful people. We have robust discussions, which is good because we try to represent a lot of the diverse opinion that surrounds these issues and try to come up with a very good balance.

In today's brief update to you, and thank you for the opportunity to do this, I think, back a year and a half ago. We'd love to have more time to work together, as we should, as I'll review in the schedule. It went pretty quickly. This time we want to do a more thoughtful process and bring it to you early and often.

I'll recap for you how we went through stage one. In a sense, we're going to use the same process. It's just going to be expanded a bit. I'll give you an overview of the process we're using for developing stage two/three recommendations, and talk about some of these philosophical issues that we reviewed with the full policy committee last week.

If you recall, it was only a year and a half ago in February of 2009 when the HITECH provision was passed, and that put into place in statute both the office and the National Coordinator. I believe David Blumenthal was appointed sometime in the March timeframe. As he and the office were trying to get together the two FACA committees, the standards committee being one and the policy committee being the other. In order to try to meet the very, very tight deadlines, Dr. Blumenthal charged the NCVHS, another sister FACA committee, with conducting a hearing to just start the discussion about meaningful use. That was done at the end of April.

It wasn't until May 11th that the policy committee met for the first time. And it wasn't until May 28th that the meaningful use workgroup had its first meeting. Between May 28th and June 16th, there was a flurry of activity to try to put together some kind of both a philosophy, as well as a framework, for organizing meaningful use, both its objectives and its criteria. And that's the blue matrix that you'll recall.

We presented that for the first time to the policy committee June 16th, got input from the policy committee, then put it out for a really quick turnaround to public comments and got 800 comments just in about 10 days. And turned that around, incorporated those, and presented our final draft on July 16th to the policy committee. Had a few tweaks there, and that became the basis for the recommendation from the HIT Policy Committee to ONC and CMS. The subsequently went through the rulemaking process and, by January 13th, put out their NPRM, which is six months later from our recommendations. And then, six months after the NPRM, they punished their final rule on the 13th of July.

Fortunately, we had more than two weeks to work on the next stages. And so during the time that the NPRM was being reviewed, etc., and the final rule was coming out, we've had a series of hearings to try to get more systematic input from the public on various issues that have come up during the creation of the framework and stage one criteria. We heard from specialists, smaller practices, smaller hospitals, safety net hospitals. We heard about state issues because the Medicaid agencies in the states regulate that part. Heard about healthcare disparities, had a hearing on patient and family engagement, one on population and public health, and concluded with one on care coordination, all looking to ask for advice on both the stage one, as well as our approach to stages two and three.

We then took, of course, the starting point is the final rule on meaningful use and the ONC rule on EHR certification, and also reviewed the placeholders we've put in that blue matrix for stages two and three. We've concentrated in that initial time on stage one, but we put placeholders there sort of to remind ourselves what direction we were heading. We've had, I believe, three meetings since then, and taking those input, try to come up with a plan or an approach to formulating our recommendations on stages two and three. Along the way, we sort of put some things in the parking lot in terms of, well, here's a fork in the road, and we could go this way or that way or a number of ways, and wanted to bring back to the policy committee, here are some of the approaches we're thinking about. Give us some feedback and directional guidance, so as we move forward, we can take that into consideration.

Let me review. One was, how do you position stage two? Is it, you just turn up the dial on stage one, or do you set some future goal in stage three, and then stage two is on the path to that, a stepping stone to stage three? Issues about migration to outcomes, we all know that even in the statute, the purpose of meaningful use is to assist providers with measuring, assessing, you know, how well they're doing, and to improving their outcomes using these tools. How quickly can we move to outcome measures as criteria for meaningful use?

The third area is in patient engagement and information sharing. I think the whole notion, the category of patient and family engagement is still one of my favorites in the sense of this is something we want owed to the patients and the caregivers. But, two, I think will provide very useful changes or additions to the whole, the care plan invoked. The engagement of patients and their families will add to the outcomes that we're seeking to achieve. Then a final area that we were discussing is just the notion of, well, are there other ways of meeting meaningful use criteria other than what may start out as essentially functional requirements of the software? I'm going to probe each of these in the subsequent slides that talk about some of the details that we were discussing in association … these philosophies, philosophical concepts.

With respect to positioning of stage two, as we mentioned, one way is to just take thresholds and add to them, or take the scope like CPOE with meds only and expand on it. Then another way, and this is actually a discussion that we had with John and John, is to look at, well, what can we hope to achieve by 2015, i.e. stage three, and then place stage two as a stepping stone to stage three? The advantage of looking at it as an incremental change and, by the way, these are not mutually exclusive. So the advantage of looking at incremental changes is the industry, the community, so that's both the vendors and the providers having to implement this stuff already know what such and such a functionality is or quality measure is. And if they continue on the path, they expand the scope or increase the threshold. They understand that.

The con of doing it just that way, meaning sort of tweak stage one, is that we will face the same problem. And one of the legitimate criticisms is can't we have a longer horizon so we can plan better? If we don't give a good signal about stage three, then it just – every two years, we have the same discussion of can't we have a longer horizon? That's sets up the approach, the second approach, which is, well, let's look at the longer horizon, and the horizon now is defined by the statute in 2015, and then try to make that sort of a roadmap, a destination. Not the full destination, but one that provides a much stronger signal, and then dial it back to something along the way.

As I explained, one of the questions we got back from the policy committee is, gosh, can't it be both? The answer is yes. We didn't intend it to be mutually exclusive. We always intended for stage two to be some kind of increment from stage one, meaning to build on stage one. But we were just trying to give a philosophical approach of saving, let's build it on the way to some better-defined destination.

Let me continue each of them and then get feedback at the end perhaps. The migration to outcomes, as we know, our goal is to help health systems by using these tools measure and improve their outcomes for the benefit of patients and the population. Imagine in stage three as achieving that. Wouldn't it be nice if we could have a number of outcomes based measures and worry less about the process measures or how they got to the what. If we were able to do that, then what you probably would have to do is set some kind of threshold. Then there's a discussion of, is the threshold the floor or a full performance kind of threshold?

If you were to establish some performance thresholds, then you could deem. You could imagine deeming organizations as, well, the only practical way of achieving these kinds of outcomes is to use these information tools, the EHRs and the PHRs as well. And that would be a much better – that would be less micromanaging, and it's really a management by objectives kind of an approach. Also, these would be a direct measure. You could attribute some of these improved outcomes to the HIT that we're asking people to install. And it supports, of course, the move towards value-based purchasing such as through models like the accountable care organizations.

Then, as I mentioned, at the same time, we are burdening. We are reducing the burden of people having to measure the processes they've used in order to achieve better outcomes. In all, in the end, it just seems like if you think that these tools are essential to improving outcomes and achieving much better performance, then probably if organizations do that, then they've used these tools, and let's not bother them with measuring individual functions.

If that were the goal, then perhaps stage two could start introducing this kind of, let's focus on the what approach. Now I'm going to give examples, and I use the adjective nearly examples just to sort of standoff any specific discussion of a specific example of saying that's something we're going to do. But the kind of thing, now this is one of the things that we did discuss, and we discussed it with John and John as well. Clinical decision support, so I think we all believe that one computerized position or provider order entry is key to realizing a lot of the benefits that we hope to achieve out of these systems. And part of the reason is through clinical decision support, the active support, both through information and knowledge presentation, at the time of decision making is how you achieve one of the major ways to achieve better outcomes by using these systems.

But instead of saying, well, you should do some of this, and I'd like to have five rules of that, and three alerts. Instead of being prescriptive in terms of how you use these systems, it's just important that you do use the function of clinical decision support, as you accomplish, as you achieve the outcomes that you seek. But it would be important, and part of the certification process is to make sure that these products, these software products give you the capabilities you need to achieve this outcome. But if we sort of enumerate the kinds of clinical decision support tools, then we pass that to the standards committee, and you would turn those into certification criteria for the product.

In essence, what we would make sure what we're going to try to supply to the industry, meaning the community of users, are the right tools they need to get the job done. And so instead of saying you must use this, this, and this specific tool, we'd like to specify a set of kinds of tools, and then you turn them into criteria that would make sure that the user community purchases has these capabilities in place. That seemed like a good trend, and this is the kind of thing we'd like to do on the way towards measuring outcomes only.

Other things we could think about … these two as outcomes oriented criteria. One of the ones we put in earlier in our draft matrix was to reduce 30-day readmission rate, which, as we all know, is around 20%

now on average, by 10% of that, and use that as a goal because really that focuses on transitions of care. It focuses on care coordination. And that we all see, you have to have an EHR. You have to have an EHR and HIE in order to accomplish those things effectively. And so if we measure that as an outcome, then it seems like that would almost mean you had to effectively use some of these electronic tools in order to get there.

Now patient engagement and information sharing, one of the ones where we do have criteria in the final rule in this category, and the workgroup spent a lot of time on how can we move this even further? The thought here again is that we want to place in the hands of patients and their families the kind of information and knowledge that they would need in order to engage in healthy behaviors and then following through on their "care plan", and recognize that there's probably a lot of innovation in this space, as we turn this information over to the patient. And we want to encourage that.

In this final rule for stage one, there are terms that are somewhat hard to understand and, as we probe into them, we understand why you had to invent a different word for a different kind of concept. But we were trying to see if there's a way to simplify things. The words like access, copy, clinical summaries, discharge instructions, and you wish it was just easier to lump it more. Actually, a subgroup of the workgroup tried to lump it and found out the devil is in the details, and it is pretty hard to separate all those things.

One way, and this is not like the way the workgroup has even adopted, but one way for me to help describe it to you is to talk about some of the dimensions sort of on our road to trying to lump these things. Although it would be nice to have a single concept or goal or objective that crosses both the inpatient and the outpatient setting, they're pretty darn different. The patients and their clinical statuses are very different, so we may not be able to lump those, have one criteria for both settings. Ambulatory care is far more in an ongoing care kind of an approach, and hospital is much more of an acute episode and much more major episode. And is the transition from one outpatient visit to another the same thing as being released from a hospital? I'm not sure.

Trying to deal with the access, download, copy, and specific use documents, one way to think about it is somewhat hierarchical. If patients essentially had access to the same things we do in the EHR, then they could do with this whatever they want and, in principle, including downloading it so that they can have a copy to take with them or to apply some other innovative tools to. That probably, if you had real time access to an on-demand availability to this, basically your health record, then that seems like that would be a fairly complete solution.

The notion of being able to walk up and getting a copy of information in your electronic health record seems like a computerized way of walking up to the HIM department and saying, I'd like a copy of my paper record. It seems like though we do need this interim step or this transition, as we move from paper to the electronic world. But as I say, if we truly had access and download capability all the time, then why would we need this copy function?

Then, finally, there are some specific use documents, particularly at the transitions of care, which, as we all know, is where the errors happen, the things fall through the cracks, and where care coordination doesn't happen. So a couple of those quick wins really is, one, clearly at the discharge from the hospital. It's a key time when a lot has happened to an individual patient, and you want to be able to transition them into their nonhospitalized setting. That's where a lot fall through the cracks. So the final rule has electronic discharge instructions, and we think that's important. Similarly, in the ambulatory setting, you'd go from one setting to another or one provider to another. There needs to be some counterpart where you can get sort of a moment in time what just happened, and how can I use this to transition to the next space.

In the deeming of external certification, this is very preliminary, but the idea here is there are a lot of new programs just in the Recovery Act and the Affordable Care Act alone. There's a lot of new potential

innovation, innovative ideas being produced. It would be lovely to have them all harmonized in a way. We certainly don't want to have people spending their time on divergent kinds of ideas, so whether it's quality measures or some of the meaningful use criteria, it would be wonderful if they could interrelate, and doing something for one program could benefit and potentially even be deemed satisfying another program, whether it's in the CMS world or with the private sector world. Again, I'm going to use hypothetical examples. It's the same thing as near examples, which is, these are not anything specific, things that we're thinking about, but just to illustrate the points.

As we all know, ACO is a hot topic as a kind of a model for ways we deliver and get paid for care in the future. Care coordination and patient engagement figure prominently in the statute and in ways before thinking about it. They happen to be categories in the meaningful use. Is there a way that satisfying the meaningful use, whether it's stage two or stage one or stage three, would be deemed as partial satisfaction of your qualifications as an ACO of vice versa?

Another area, which is very interesting, as you know, the boards of medical professional societies have certification as getting board certified in the initial case. Then they have maintenance certification, so there are activities. The have exams to maintain your certification. But they're also incorporating, well, how are you measuring and improving your care to your patients? It's sort of like a practical part of it.

Well, one of the modules, the practice improvement modules, actually ask for you to extract data from your paper record initially and show that you use list patients to measure and improve their care. We can see where clearly all of us would want to go to an electronic version of that and, again, could. They deem an activity that we're asking for in meaningful use, for example, use of patient lists to improve care, as partial satisfaction of some of their requirements or vice versa. That's very exciting because we're now changing. We're much more directly changing the practice of medicine by leveraging some of the activities in the professional associations and societies.

One of the points that David Blumenthal brought up during the meeting was, could there be tracks, so it still goes back a bit more towards the outcomes discussion that we just had, which is, gosh, if you're already a high performer, and clearly you must have had EHRs or electronic information infrastructure in order to accomplish that, then do we really have to put through the hoops of did you use this from your EHR, and did you use that. That's another idea.

Let me close with sort of a work plan timeline. We got some directional guidance from the policy committee last week, as I mentioned. We're taking that back to the workgroup. We'll use that to continue to work on the individual criteria for stages three and two. We're due to present that first draft of our criteria back to the policy committee December 13th at that meeting. Then taking into account some of the feedback from that group, we'll put together a request for comment. It's very similar to what I said in stage one.

That'll be released, trying to avoid the holidays this time, in January for public comment. We'll take those comments back in February and try to revise our draft criteria and present those and get more feedback from the policy committee, heading towards a final submission of the HIT Policy Committee's recommendation to ONC and CMS in the summer timeframe, very much analogous to what we did with stage one. One of the reasons to "wait" for summer is because we wanted to get as much information back from the field as possible, both through the submissions of information to CMS for stage one incentives, but also feedback from the regional extension centers and all the other feedback we can get in response to stage one, and try to take as much of that information in as possible on the way to producing drafts for stage two and three.

We're sort of between a rock and a hard place in terms of timing. Everybody would love to have more time to prepare for stages two and three, but we also don't want to ignore what's going on with stage one, as was presented earlier. Then there's a clearance process and a proposed rulemaking process that means that the final rule cannot be released with an 18-month lead-time that was desirable. So the

negotiation is, can we give the industry enough signals, strong signals, sort of like our track record with stage one, that at least we can point them in the right direction, as they await the final rules coming out from CMS.

With that, I'd like to turn it, open it up. George, do you have anything to add there in terms of the presentation of what we've done?

George Hripcsak - Dept. of Biomedical Informatics Columbia University – Chair
No, that's great, Paul. Thanks. On the thing just pointing out on the end there that some of the data we'll be pulling in are the Vanguard meaningful use adopters identified by the regional extension centers. In general, the regional extension centers should be providing earlier data than CMS will get on actual submissions. But you more or less said that in that last part, so that sounds good.

John Halamka – Harvard Medical School – Chief Information Officer
Great. Thanks so much to the both of you. I just want to start with a couple of comments, and I'm sure there will be a rich discussion to follow. What I hear from the industry is we really need to understand direction, and it's very challenging to say, we're actually going to put all development on hold for a year and do this. Then we're going to change direction and do that. So to say here is the plan generally to stage three, and here are the interim steps to get there, I think would be very, very helpful to the industry. Certainly understand the pros and the cons and the reason to have pieces of incremental stage one to two, but just to sort of hear overwhelming support in the industry for a use stage two as a stepping-stone to stage three.

When I look at your hypothetical, merely kind of examples, which of course we recognize are just early ideas, I wonder if stage two and stage three, which starts to get more outcome focused, is going to require more of a community focus than a single EHR database focus. It's very challenging to say, if we are a collection of hospitals and clinics and pharmacies and labs, what the outcome is unless there is some more of a community aggregation of interchange of data to measure such outcomes. If we in fact do declare a community focus for two and three, then there will be a lot of standards that I think will need to support such pull rather than push types of transactions.

Patient engagement, I agree, is an incredibly important topic, and I refer everyone to a blog entry that Josh Seidman at ONC wrote a few days ago on the ONC blog, and this is one where he, a relative of Josh's, came to my hospital. Of course, since Josh is the director of meaningful use, I wanted to do everything in my power to give a meaningfully useful hospital experience to his relative. Of course, what I did, Paul, was I provided immediate access to real time data around all aspects of the hospitalization, a copy of the lifetime health record, including the episode of care in a standards based format, as well as a hospital discharge instruction in an XML form, and then Josh wrote this very thoughtful blog on the good and the bad. So I now have this wonderful XML form of my lifetime medical record. If I have an internist that lives with me, that's helpful. Otherwise, what does it mean that my hemoglobin is 12.2 and my sodium is 137, and these six tests were ordered?

What it suggests is it isn't enough to just provide access or copy. You must wrap that in educational materials that make it actually a useful construct for the patient. Anyway, I highly recommend you read that blog. There are about 11 comments that have been very thoughtfully added to that blog as well.

A point I think for the standards committee in creating these documents, we all, I think, recognize that CCR and CCD had a particular design construct to be transitioned documents. And, as structured, have problems, medications, allergies, labs, that sort of thing. Discharge instructions, discharge summary, not really something you can represent to either CCR or CCD, so what we've done is taken the CDA and some of the constructs that HITSP had originally worked on in C83 and taken pieces of C32, the CCD, and then added other modules to it to create these specific documents that you suggest. I do think this committee is going to have to work on approaches to representation of specific documents that are commonly used in healthcare, both structured and unstructured.

The last thing, your timing is December 13th for your draft meaningful use stage two three criteria. We are meeting on November 30th virtually and December 17th virtually. And so I would say our December 17th meeting, if possible, Paul and George, if there's a way you could join that call so that we could have a discussion of your December 13th deliverables.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Sorry to jump in on the phone. I just wanted to say on your last comment, I hope that the standards committee, in general, can have a conversation about this sort of path we seem to be going down with document creation and registries. I think we should really discuss that at a fundamental level and talk about the objectives and how to best achieve them. I have … which I've stated before, which is that I don't know that we're going to get to all the documents and use in healthcare, and before we create a lot of complexity, we should just think through the objectives and what the best way to get there might be.

John Halamka – Harvard Medical School – Chief Information Officer
Certainly. In previous meetings, what we have talked about is not, as Carol highlights, creating 1,000 new standards for every flavor of document and form, but more to say, is there a generalizable container that could be reused over and over again, and module enough that individual organizations could include components in one standard stack, not 1,000. Certainly, Carol, I'm sure we will have ongoing discussions of that philosophical point. Many, many cards around the room, so why don't we start with Jim Walker?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I want to address process measures and outcome measures. Clearly patient outcomes are the game, and where we have to get to and the issue. The problem is that process measures are leading indicators, and outcome measures are lagging indicators. That isn't so much a problem in very large organizations like ours because the populations are big enough that, if we do a good job, the outcomes should be apparent.

The problem is, there's careful published modeling that demonstrates that even in the very most effective therapies, aspirin for acute MI, it would take an average size hospital years to have enough patients to show a difference between a hospital that did a perfect job and a hospital that did a bad job of that process measure. And so, I just want to encourage us, as we make the appropriate transition from particularly paying attention to structure, which really is pretty much the CDO's own business, that we really nuance our understanding of process measures and outcome measures so that we don't lose the ability to measure the quality provided by smaller – small practices will not have enough population for almost any outcome measure to be statistically meaningful. And even small and average size hospitals won't.

The second thing is that while we will provide reimbursement more and more for outcomes measures as opposed to process measures, organizations will still need to measure their process performance to understand why they're achieving outcomes and why they're not. Obviously all organizations that provide high quality at low cost manage their processes like mad and measure them very, very carefully. And so, at some level, again, except for the very most robust organizations, the other organizations are going to need guidance and support in managing their internal processes to get to the outcomes and be able to tell perhaps why they aren't getting to the outcomes and change their processes.

In some way we need to – well, it would be very – we're more likely to get to outcomes if we provide those smaller organizations with standard process measures that have been shown in validated studies to be linked to outcomes, and then we update that when we find that some of those punitive or that some of those process measures don't actually correlate with outcomes. That's one of the other things we're going to need to research and measure and feed back to organizations so that, again, they can manage their processes optimally.

John Halamka – Harvard Medical School – Chief Information Officer

Great. Paul, George, any comments on process versus outcomes orientation?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Actually, I have some comments on most or all of the comments, I guess, which I think this is a rich discussion. Let me start with where you started, John, with some of your comments on the community focus and the patient experience because I think this has a lot to do with the standards committee. Maybe this is a good time to start feeding forward.

The community focus and HIE, it's definitely the place we want to go to. And in fact, it's been said that because we obviously couldn't in stage one in 2010, force the exchange with organizations when there's no exchange vehicle in most communities. But we did, there's been a thought of wanting to focus in on this whole exchange thing in much more depth in stage two. That puts the front and center focus on the standards and the exchange – well, the exchange standards from HIT Standards Committee, so we would love to have more of your input, even on what you think we can be moving towards in stage two, which is 2013. It's not that far off.

The other piece you mentioned was the patient experience. So what am I going to do with my XML document with all of this Greek stuff in there? If there's an issue, one of the things in our initial draft was to have patient specific educational material. That's to counter the kind of Xerox, the heart failure discharge instructions on every form. That originally got taken out, and it was one of the things that we "wanted to" on our feedback on the NPRM, we wanted to put back in, and it got put back in with a 10% threshold.

But where standards committees can come in is, well, how are you going to get patient specific if we don't have a good way, standards that say, well, how do you tie back to what's going on with this patient? This might be a discussion of SNOMED versus ICD. And, of course, in 2013, it should be ICD-10, but will we be patient specific because of their ICD-10 or SNOMED, or do we say the way you become patient specific is to understand them in the clinical terminology of SNOMED? Again, these are all hypothetical, but these are the things that the HIT Standards Committee could help by weighing in on those kinds of choices.

Jim raises a great point about the outcomes, and we actually had the same point raised at the policy committee. First of all, I want to say, by outcomes, we sort of mostly mean intermediate outcome measures because, as you mentioned, it's really a lagging measure when you get to outcomes and this challenge of small numbers. So I think where we're headed is you may or may not know, there's a separate workgroup that was formed about six weeks ago that deals with "quality measures". We're looking for quality measures that are both HIT enabled, that is, you probably couldn't efficiently get these unless you had an EHR, and HIT sensitive, which means that the scores or results that you achieve, there's evidence to show that it is linked to the HIT support you have. I think the goal there is to rely more on these HIT sensitive measures in order to assess whether you are a meaningful user of HIT. But anyway, these are really good points, and I'm writing them down to bring back.

George Hripcsak - Dept. of Biomedical Informatics Columbia University – Chair
Paul, let me just say, on the first issue related to the patient getting their data, meaningful use can't solve everything, so the fact, I mean, maybe what happens is meaningful use creates a market where patients have all this complex data, and a third party helps them interpret it. In other words, we can't guess everything that's going to go well or all the benefits that will accrue from meaningful use, but we can create a system where there's an opportunity for third party vendors or whatever to help, let's say, the patient interpret. So kiosks would be the kind of company that could potentially go to the patient and say, look. Send me the CCR or send me the CDA document, and I will give you an interpretation without us from meaningful use mandating the creation of that market. I think that some of the tests could be left a little bit open and not solve to the Nth degree.

On documents, those are very good comments. We have a conflict even within our sub-workgroup of do we want a discharge summary, discharge instructions. They already exist. There's a concept in the community of what they mean, although they may not be a full standard that everybody agrees to. Maybe we don't need to fix that. What we want to do is just define, okay, if the patient is getting the record, what do we mean for now? Do we mean the entire document and scan in all the history, or do we mean just the key clinical features that that patient needs? That's something that maybe we could, working with you, we could define now without redefining what is discharge summary, without redefining what the discharge instructions mean, so they become components in this bigger document that we say comprises a full record for our purposes for now.

John Halamka – Harvard Medical School – Chief Information Officer
Excellent comments, and I think you've teed up a couple of discussion points for our November 30th meeting that will be the intermediate meeting before we have the full answer as to what stage two and three meaningful use might be. The issue of how do we create standards that foster community, and how do we deal with some of these issues of document and registry creation, and some of the standards that might be necessary for those, so very happy to work collectively with you. Jim, did you have a follow-on comment?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Two additional thoughts about this: One is that from our experience in our beacon where we're trying to do this kind of thing, run care coordination out across an entire community of non-owned organizations, including nursing homes and home health, attribution is going to be a real trick. The thing about care coordination is it brings lots of healthcare team members together. The tricky thing is, if it doesn't get done, it's hard to know why it didn't get done. We actually designed our beacon community. Just sort of, we have control over enough of it that we can be responsible for getting the process done, but that will not be the case just in the standards setting.

The other feasibility question is about health information exchange. This will place, you know, the care coordination standards are likely to place a very large burden on health information exchange. It's unlikely that a significant proportion of the provider population will have access to anything like high enough performing health information exchange to achieve anything that requires that by 2015 even. So we'll need to be very smart about the measures that are somehow in the control of the CDO.

John Halamka – Harvard Medical School – Chief Information Officer
Kevin will go and then, Wes, you'll follow.

Kevin Hutchinson – Prematics, Inc. – CEO
I'm going to echo a comment that Carol made earlier, and actually respond to John. On the CDA, CCR, I think one thing that we just need to make sure we do as a standards committee, as a policy committee is that we focus on. We say the word documents, but really we're talking about computer documents that have content inside of it that can be used for a variety of different things versus the forms that each hospital or each physician uses. I think, as a goal, as a committee, both on the policy side and the standards side, is that we should focus on how we can write something once and use it many times in various different forms versus very specific documents or uses of exchange of information, as Carol was alluding to. I would support what Carol's statements were.

I also think that, and this is for Paul and George, your benefit as well, I get asked this a lot with respect to the work that we're doing around meaningful use is that the purpose of the policy committee and the standards committee to create a comprehensive set of everything that we will need in healthcare to create a meaningful use and measure the comprehensive outcomes, or are we going through a process by which we are establishing the critical requirements, the baseline, the foundation by which the industry will continue to build upon, utilizing some of the standards that have been created. But I think, whether it's PR or just a communications perspective, we should make it clear to the community where we stand

on the goal of being comprehensive in nature or minimalist in nature where we're putting the minimums of those thresholds.

Paul had alluded to minimum threshold versus something more comprehensive, and I think there's some confusion around that. If people are waiting around, waiting to see if the policy committee and the standards committee are going to create this wonderful document that's going to be comprehensive in nature, that's going to solve all of healthcare's problems, or are we simply trying to jump start the car to get it moving in the right direction that requires this minimal set of standards.

John Halamka – Harvard Medical School – Chief Information Officer
You've made two very good points. The first, in many writings and presentations that I do, when I say the word document, it creates confusion. What I really mean is a collection of data atomic elements that are reusable for purposes, and maybe there are maps that relate the data elements, one to another, but this is not a document in the sense of a word document. And so the standards that we talk about are all codified and structured and data elements relate one to another, and a document is purely a collection of individual elements. That's all it means.

In terms of what this committee does, one would imagine that with our implementation workgroup, we're removing barriers where they exist to commerce and care coordination and population health measurement. But, generally, I think of certification criteria, and Dr. Blumenthal has joined us, so he can shake his head if he agrees, as a set of foundational elements that represent a floor of what we are trying to achieve rather than a comprehensive solution to every problem in healthcare.

David Blumenthal – Department of HHS – National Coordinator for Health IT
This is David Blumenthal. I would hate to think that we are defining a ceiling for what the industry can do or what any individual healthcare organization can do. I think we're defining a set of objectives that are consistent with that justify the payment of incentives. That's sort of what the meaningful use framework is literally about. Now they also hopefully will get us on a trajectory towards more and more comprehensive, sophisticated uses. But, gosh, we really hope that the industry will just go way beyond what requirements we're setting, and it is. It is. Some of the organizations are at or beyond meaningful use already. Absolutely, we're just putting in place – it's not a floor. It's more than a floor. It is an aspirational goal, but it's not the ceiling.

John Halamka – Harvard Medical School – Chief Information Officer
Wes, go ahead.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks. I want to comment that sometimes one of the penalties of participating in a FACA is that you can't join in all those sessions over a beer and complain about all that stupid stuff the government is doing. One of the ways I try to characterize what's happening is that some of the meaningful use criteria are like indicator species in an ecosystem. You can't measure the whole ecosystem, so you pick sensitive sub-factors of the ecosystem and look at those.

I want to say that as the policy committee moves forward, there are a couple of issues that have been mentioned that I want to talk about a little differently. An incentive is an incentive if the party that you're trying to change the behavior of believes that with diligence and investment, they can meet the incentive. To the extent that you place requirements on those policies that they cannot meet on their own, that they require other people in the community to meet, and yet there is no value based purchasing or other economic tie between the elements of the committee that has to work together. You risk making the incentive uncredible, and then that's not necessarily good for the overall program. That applies clearly to interoperability.

What I think we tend to envision is the stages of meaningful use raising whole communities or the whole country kind of evenly like the tide raising. In fact, there will continue to be substantial variabilities in the

ability of physicians and the willingness of physicians to adopt EHRs and the ability of communities to organize themselves to share information. I think it's important that we keep that in mind, as we talk about documents as collection of data versus documents as human readable forms. I would say that even applies to the blog posting about the person that was in John's hospital.

An important characteristic that we have is a dual use of documents. They can be printed, or they can be ingested into a computer system. We need to not lose track of that. I think it's also important to recognize that, in the spirit of the ultimate government initiative, that transparency is not always about creating data that is equally understandable by the entire community. It's partly about trading data that can be understood by the people in the community who want to put the time and the skill into it, and can advocate for the rest of the community, or at least inform the rest of the community. I wouldn't argue that giving data to a patient without giving guidance is not useful.

Finally, we're clearly in a bind between how much we want to emphasize measuring processes and how much we want to emphasize measuring results. The meaningful use goals will be an intermediate position there. But I'm wondering, are we risking creating yet another set of guidance on what outcomes are important to physicians and hospitals who already have so many different sets of guidance on this issue, or are we better to focus on measures that demonstrate the enablement of IT under the incentives program, and measures that demonstrate the effectiveness of the hospital organization, IT and other things considered in other programs. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer
All very good points. Wes, I think your point about the uses of data certainly suggest there may be different forms. Sometimes human readable is sufficient. Sometimes codified is necessary. If you're transmitting information to a patient and their family, human readable is probably totally fine. If you're measuring quality, it probably isn't sufficient. You're correct. We always must keep in mind the intended uses of whatever it is that we suggest as a transmission form.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
John, I'm actually trying to make a point further that we often need, because it's not a rising tide, it's more like a rising earthquake, but different levels of adoption and sophistication around the country. We have to keep in mind that we don't actually know the usage it will be put to when we send it, and that we need to send it in forms that are suitable for multiple uses, as opposed to being, assuming that much knowledge about the receiver when we're creating the emission here there's going to go out.

John Halamka – Harvard Medical School – Chief Information Officer
Right.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Amen.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I'd like to endorse that. We have a phrase that we use when we think about data preservation that we talk about as preservation of causality. You don't want to simplify the data to too much levels of abstraction because you will blur causality. You'll lose the information that's necessary to go back in time and look and see what happened. So that the two foci, I think, on data copies, the issue about access and copies should be data liquidity. We've got to be able to move the data to other places, and then preservation of causality. Preserve as much of the data as possible because we don't know what's going to be valuable until we can look back.

John Halamka – Harvard Medical School – Chief Information Officer
Right. Very, very good points. We have some other comments in the room. I think it's Dixie, Janet, Walter, and Anne.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
First of all, I like the idea of bringing the accountable care organization in your presentation, Paul and George, and also the community idea because I think that that's where we really want to be is measuring outcomes across a continuum of care and not just in one specific place among that continuum. I was thinking about this actually when the implementation workgroup was talking about the plans for the hearing in January. I think, even though the ACOs didn't come forward and fill the reform bill, it would be nice to include the ACOs in that hearing, in the implementation hearing.

The second point has to do with this documentation idea and communicating with the patients. I think it's important that we provide patient's information that they can understand, and I also think it's important that we not decide what the ceiling is for their understanding or, as Wes has pointed out, that we not decide how they're going to use that information. I like John's suggestion a while ago of a structured container into which we can load structured data and through which we can – which can be exchanged with patients and also presented with patients at whatever level they decide they want to see it.

You may be aware of this, but the tiger team recently made a recommendation that the notice of privacy practices be presented in a layered approach whereby, at the top layer, if they really didn't want to see all the ten pages of notice of privacy practices. They could see a very articulate, short summary of here's how we use your information. Then if they really wanted, if they were an attorney, and they really wanted to read the details, they could go at lower and lower layers. I think that that makes sense for patient information as well. That through this structured container, that it be able to be presented at the very top level where it's just basic. Here are your discharge instructions, or if they wanted to dig down at deeper and deeper levels, that they're able to get more information in a more structured form.

John Halamka – Harvard Medical School – Chief Information Officer
Right. Then it was also mentioned, the notion that there may be an ecosystem of vendors that could take that and present it in novel ways. Some might be graphical, and some might be in lay language. And it is up to me as a provider organization to provide the data elements, but it may not be me that provides all the educational materials because it's hard for an individual institution, even a large one to do that. Good point. Janet?

Janet Corrigan – National Quality Forum – President & CEO
Thanks a lot for a great presentation. I think it's real helpful to hear what the other group is doing. A couple of questions following up on the comments that have been made, particularly Jim's comment about attribution. This fear of attribution issue a real challenge. I think, in recent years, it's had a negative impact on measure development. It's amazing how creative measure developers will be to be able to try to control attribution, both the level that it's at or exactly how the attribution will take place. And I think we have to find a better way to deal with it because it can be a major impediment to kind of moving forward, the fear of attribution at too low a level, especially when it comes to the outcomes area, which I agree is important to go at.

And I just wondered if there was some creative thinking going on. I'm sure there probably is to try to move the reward pools, whether it's HIT incentives, whether it's the shared saving pools, shared savings reward pools under the payment demonstration projects, up to the community level because it's going to be a while before we have ACOs developing. There aren't that many of them that really exist at this point. It's a new movement, and they have to kind of evolve. But if we want to move more rapidly, and if the proper level for attribution for many of these outcomes, and I don't mean the intermediate outcomes, but the more final outcomes like health functioning and health behaviors, really is more at the community level. We need to figure out how to get financial rewards out there and tie them very directly to those measures and provide some assurances to clinicians that you're not going to take health functioning down to the individual clinician level. I think there has to be sort of a messaging and an educational effort that helps assure people that this information is going to be used responsibly when it comes to doling out the financial reward and the new mechanisms.

But then I have a practical question about your timeline, Paul, that you went through on the meaningful use work plan. Last year, for the 2011 MU measures, the policy committee brought forward concepts of what they wanted measured, and the standards committee then went out and identified performance measures, and then brought through the HIT implications. For 2013 and 2015, the process was clearly different. The policy committee will be not only identifying those concepts of what they want measured, but also the performance measures themselves. What isn't displayed on your timeline is some sense as to when the actual performance measures will be there.

My understanding is there are going to be RFPs to do rapid development of performance measures, but that's another difference between 2011 and 2013. In 2011, given the timeline, we only could work from measures that already existed, whereas in 2013, the effort is to go out and get what you really want and need. But I think it would be helpful to have some communication, as that process evolves, because if you get those RFPs for measure development in the field by, say, December of this year, you're going to have a lot of activity made by March or April. You'll have an idea of how those are shaping up, but it's going to be right down to the wire in terms of timing. Jamie's workgroup is going to need some sense as to how those measures are shaping up to be able to look at the standards implications.

Now hopefully, since so much work was done in that area in 2011, and I'm assuming that even for many new measures, that the actual HIT standards implications will perhaps have been spoken to already because they draw from the same general area, although they may be different measures. But for particular areas of measure development, what we really haven't reflected in 2011, like some of the creative care coordination, like some of the outcome measures, if we actually get to some of that point in 2013, or virtually anything that's patient derived data, those are areas that I don't think this group has thought about hardly at all, and they're not going to be reflected in the HIT standards work that was done for 2011. As soon as that starts to evolve, it would be good to have a heads up because probably Jamie's workgroup could begin working on this even before he had fully developed measures.

John Halamka – Harvard Medical School – Chief Information Officer
Paul, George, comments?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Actually, I think the person who has the most knowledge about this is Dr. Blumenthal. Not only does he chair the policy committee, but he chairs the quality measure workgroup.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you for that, Paul.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
I could talk a little longer, David.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I think there was a blend in the first go around of meaningful use. I think that the policy committee did actually come up with a lot of measures, a lot of objectives that implied measures. The quality measures, we did turn to the standards committee in part as a recognition of, Janet, your expertise, and the expertise here to assess the existing measures and give us a sense of which had standards. We were kind of confined to existing measures.

We hope to have a new set of proposed measures in good time. Now the question is, what's good time? It would actually probably be helpful for us to know what the amount of time is that's required to develop standards for newly proposed measures and what the standards, how much time the standards committee would need and how that might affect the calendar.

Keep in mind that we can propose measures in the NPRM and then withdraw them if the standards aren't ready. We did that in the first go around of meaningful use, and actually we can accept comment on and invite comment, including comment from you, about whether the standards are ready for a given set of measures. In some sense, the NPRM is an opportunity to refine and test the public's understanding and reception of the measures that are promoted or put forward by whoever put forward measures. If you think of it that way, the work of standards creation doesn't end with the recommendations of the policy committee. It can be going on while the policy committee is working and for almost six to eight months beyond that as the NPRM is put together, and then as we accept comment on the NPRM. Still, it would be helpful to know, if you all have fairly fixed or clear time requirements, what those would be.

John Halamka – Harvard Medical School – Chief Information Officer
Walter?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes. I have a couple comments. The first one, and this builds on several of the comments that have been made, but I'm going to give it a little bit of a different perspective too. The first one is regarding the interdependencies that I'm beginning to see as the new directions for stage two and stage three are beginning to take shape. Particularly the one that has been highlighted, which is elements that relate to HIE and how the HIEs are going to be now critical in order to be able to achieve some of the possible measures on outcomes based areas for stage two and stage three. In many respects, while there is certainly the benefit and the value of insuring that organizations that are going to be adopting electronic health records also begin to connect and communicate through HIEs.

I think the risk or the challenge is really to figure out how some of the measures are going to be measuring more of the ability for organizations to not just be connected, but connect and exchange data through organized information exchanges within a region. And so, in many respects, these new measures will begin to cover areas that might be a little bit out of control, of the control of the organization that is implementing an EHR, and there's that concern. I think, in developing the measures, and in recommending the measures, it's going to be important to look at the two aspects of this: the HIE portion of it and the HIT, the electronic health record portion of it.

David Blumenthal – Department of HHS – National Coordinator for Health IT
That point has been made by a couple of people here, and it's a very valid point. This is the dilemma we face that there is, in healthcare communities, substantial reluctance to vigorously exchange information. And one way of avoiding exchange is to say, that measure is not good because we don't control it. Well, the question is, could you control it if you put your mind to it by developing teams of networks of providers that work together. In effect, the lack of control argument is a little bit like saying we choose not to control the care of our patients because it's not either socially or culturally or traditionally or economically comfortable for us or in our interest.

I think we have to keep our focus on what's good for patients, and if there's some tension created around people's needs to get out of their comfort zone in working together in local communities to make care better for patients, that may be just one of the healthy tensions that is inherent in this process that were engaged in. We can't reform the whole health system through the meaningful use framework. We should and need to be working with our colleagues elsewhere in the federal government through working on, for example, the medical loss ratio requirements so that insurance companies are also incented to participate in promoting exchange of health information since they are major beneficiaries of exchange.

We should be working with the Medicare innovation center in its efforts to change and incent changes in the local organization of care. We should be working with the accountable care organization process and make sure that accountable care is not used as an excuse to inhibit exchange, as people try to build their accountable walled cities in local communities and grab local providers and tie them in, in tighter financial incentives, including EMRs. So we need to do all those things, but I don't think we're going to be able to

stay completely within the comfort zone of local providers if they're going to move in a patient centered way towards the use of health information technology.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I think articulating those thoughts and those perspectives as almost preconditions to the state two and state three, and expectations. I think it's going to be very, very important because that's going to give the industry a new way of looking at meaningful use. It's not just me adopting an EHR and trying to do things internally. It's me adopting it and now trying to communicate externally and improving the care through external exchanges. I think those perspectives that you just articulated would be very critical to putting sort of a background introductory precondition document around stage two and stage three.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I don't want to dominate this agenda, but we have been saying that. We have said it. The way we've said it is information should follow patients.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes.

David Blumenthal – Department of HHS – National Coordinator for Health IT
And if your patients are not getting care exclusively in your organization or your practice, your information should be accessible at least on request to those other organizations. I can't tell you the number of times that in my travels, which have been pretty extensive in the last couple of months, dozens of cities and many, many healthcare organizations, I hear people say my hospital doesn't want to do this, or they can't exchange. Even two versions of the same vendor's software can't communicate with each other. And I'm thinking, boy, that's not a technology problem. That's a problem of will. And within the limited authority that we have under meaningful use, we are going to keep pushing that boundary because the standards will become standard if people have to exchange information.

John Halamka – Harvard Medical School – Chief Information Officer
I'll say you are not going to get extensive use of data exchange until there are … incentives to do so.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I'd like to comment on that. First, thank you. As the operator of the only HIE in Pennsylvania that is not just a business arrangement among an internal business arrangement, we're grateful for everything HHS does to make the business case for people to participate. Having said that, I think it's useful for the committee to understand the reality on the ground. Right now, the rate limiting step for us is how fast we can connect organizations to the HIE. It costs us about $20,000 and X amount of people's time. We're moving through it expeditiously, and we can manage most of the people who see the business case now.

If everyone saw the business case tomorrow, and everyone will sometime soon, but if they all saw it tomorrow, we could not hire and train enough people to connect them all maybe by 2015 at some outside, but it would be a miracle. The state has said repeatedly that it is not going to connect people to the state HIE because it's hard work, and they don't have the skill sets. And so I think that's the reality we're up against in terms of building that technology into measures is that it just – and there are beacon communities in states that there is no HIE, and part of the beacon community process is to stand up an HIE. So we're not the tail end of this thing. That's the concern is that we do everything possible to make it clear, if you don't share information, you're out of business within some short period of time, without making it so that people just can't do it.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I do have a second point.

John Halamka – Harvard Medical School – Chief Information Officer
We are running slightly behind schedule, but please ….

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I will make mine very quick. The second point, which is also a larger scope point, so we have this question about HIEs and HIT and the degree to which there's interdependency. The other part is really the question about the measurement itself. I think Jim mentioned the process and outcome measures, and there's been a lot of discussions around that. And there's been mention about attribution in the context of attribution of consumers or how much accountable care organizations can be attributed to the outcome of a particular patient.

My question is really about the need for having a much larger national quality measurement and performance measurement framework of which health IT is a contributing element to it. The concern that I would have over some of the measures is the degree to which one can isolate the effect of HIT on the outcome itself, on the actual measure. Some measures are clearly 80% or a large proportion of the actual measure and the actual outcome is attributed or can be attributed to the health IT itself. But in some other cases, there are a lot of other factors. One good example is the reduction of 30-day readmission rates by 10% as an example.

Yes, health It will be quite valuable to be able to identify that, so the question is, to what extent are we using not so much anecdotal, but evidentiary documentation of the degree to which measures can be backtracked to the health IT and the degree to which the health IT can contribute to the actual outcome of that measure. It's really that element that I think is more of a question for both, I guess, the policy committee and the work that is being done to identify meaningful use stage two and three measures, the quality workgroup specifically. Then also, when things come back to our committee in the standards world, to what degree can we look at how a measure is affected by the HIT itself?

John Halamka – Harvard Medical School – Chief Information Officer
In a sense, IT enablement measures, as we've discussed a couple folks have mentioned so that you can get a sense of what people are doing. It may be challenging to relate a specific IT enablement activity to a specific clinical change, so how do you set this balance between measuring an IT functionality and process versus the lagging indicator, as Jim said, of outcome, which for especially small populations, it may be very hard to measure. We have Anne, Jamie, and Chris.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
I'm a payer, and we talk a lot about the ACOs, and I see a big set of incentives for people to start playing correctly is there payments, their reimbursement is going to change. Not just the force of having an electronic health record, the rightness of coordinating care, but the reality of your reimbursements are going to be judged based on the quality of care in some way, which brings me to my point. For meaningful use two and three, a little more discussion about what kind of data the payers might need so that there's not another administrative nightmare that is built after we go through this exercise that has to be put in place in order to support us to know that those payments are being made appropriately. Some representation on that, which I think is really a Wes and other commenters on make sure the data flows through so that it can be analyzed at all levels. This is another constituency that's very important to the success of this process.

John Halamka – Harvard Medical School – Chief Information Officer
It's also, again, as I said, the industry really wants this direction so that it has time to build the tools. If you're doing ICD-10 and 5010, and then suddenly we tell you, by the way, here's a whole other infrastructure you have to build. You have 18 months. That can be challenging.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
We'll give you 20% of your incentive under this coding structure, 30% under this coding structure, and it could be a very big nightmare, so it's just one of those stacks of constituencies that are building reasons why this is a very important thing.

John Halamka – Harvard Medical School – Chief Information Officer
Thank you. Jamie?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. Two items, one just a very brief comment. I wanted to support the idea that was raised in the presentation that high performance on certain measures could potentially satisfy some meaningful use categories. I think that was raised as a question. I think that's a really good idea. But in the interest of time, don't want to go into that in greater detail.

But the other thing is just really a simple timing issue because we heard just a short while ago from the implementation workgroup that they're having two days of hearings on the actual implementation experience from stage one. And that's going to happen about three weeks after the draft is supposed to come out from the meaningful use workgroup for stages two and three. It seems to me that the sequence of those things is backwards, frankly, because we heard a desire to have the experience of stage one inform stages two and three, and yet we're hearing about it three weeks after the draft is coming out. So if those two dates could be switched, that would be great.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Let me just add, I don't know when the hearing is scheduled for, but the fact that we have our initial draft going before the policy committee has nothing to do with – it's not even close. It's just the beginning, so that's not a particularly important date that we have to hit.

John Halamka – Harvard Medical School – Chief Information Officer
My understanding, looking at your overall timeframe, is that you were actually going to wait for second quarter of 2011 to get a report from CMS on the success of meaningful use stage one before you would actually make your final recommendations, which would not be until third quarter. So we do have some time.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Yes, we have time, and I hope we can participate. Well, I hope. We will certainly take advantage of the results you get from your hearing. That's really good input.

John Halamka – Harvard Medical School – Chief Information Officer
Of course, the challenge in scheduling a hearing is, given holidays and other schedules, what's the right time to get critical mass.

Judy Sparrow – Office of the National Coordinator – Executive Director
And we also picked January as the hearing time to get past the holidays and try to avoid the … weather in D.C. So we were trying to keep all those little ingredients … although we're all here in the rainstorms, right?

John Halamka – Harvard Medical School – Chief Information Officer
Right. So as long as Paul promises to us that if we have these feedback sessions in January of 2011, that gives us plenty of latitude for revision. Then I think we're probably okay. Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
First, I completely agree with what Jamie had to say, and it sort of is related to what I would like to say around process and outcomes measures that Jim talked about initially. You know, it's just an observation that for a lot of practices we're asking them to make the move from no technology to initial implementation of technology to change in process using technology, to connection of practice using technology, which will change their business processes, all in a very condensed period of time. It's just a fact of where we are, and it's something we need to do, but it's just a fact.

I fret a little bit about, let's say, the bottom quartile of the industry that may not make it. The top ones might do a great job in aligning outcomes with measures, with standards, and do great. But I don't think you can lower the bar, and I don't think you can make it easier because we won't get where we want to. So I would make a recommendation, which is intended to be practical, which is, for stage two and three, a blend of outcomes and process measures seems to make sense, and I think one of the sort of geneous things of the stage one rules was a combination required in menu items. And there may be some organizations that, for reasons that Jim gave, or simple, immaturity in terms of their ability to adopt, may not be able to hit an outcomes bar. And perhaps a good set of process measures that sit alongside outcomes measures might be a good way to deal with the bottom of the market, while we're still setting some aspirations for the top of the market.

John Halamka – Harvard Medical School – Chief Information Officer
Very wise. With that, a great discussion. Paul and George, I want to thank you very, very much, and we'll look forward to watching your work and then having a significant amount of input. Together, we hope that we can achieve a set of meaningful use criteria that are implementable, have timeframes that allow all this business process change to occur and are practical.

M
Thank you, guys. This is wonderful. Thank you very much.

John Halamka – Harvard Medical School – Chief Information Officer
And our work will never be done. This is wonderful. Full employment. Thank you.

M
Thank you very much.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
It's really good.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Full and competent employment.

John Halamka – Harvard Medical School – Chief Information Officer
Of course. Let us now move on to Arien and Doug's presentation. And I recognize, in terms of the total time allotted for this committee meeting, we are on schedule, but because we jumped ahead early in the meeting, but Doug and Arien, how is your schedule? Are we okay with regard to your timing? Doug has said yes. Arien, you're on the phone?

Arien Malec – RelayHealth – VP, Product Management
I am here. Yes.

John Halamka – Harvard Medical School – Chief Information Officer
And … flexibility, yes. Okay. Very good. Doug, how would you like to structure this? Would you like to go first, or Arien go first?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I actually think Arien should go first. Arien?

John Halamka – Harvard Medical School – Chief Information Officer
Arien, I had introduced your presentation as a report on the NHIN Direct project, what lessons we could be learning from governance, where you are in your technical implementation, and that this is really a session where the HIT Standards Committee can ask serious questions and validate your approach.

Arien Malec – RelayHealth – VP, Product Management

Excellent. That's wonderful. I would first like to say, it's always a pleasure to come after an update on meaningful use. It certainly puts the work that we're doing in an appropriate context, and it also makes the overall timing always fun. Do we have the presentation up?

John Halamka – Harvard Medical School – Chief Information Officer
If you could forward to Arien's presentation.

Arien Malec – RelayHealth – VP, Product Management
Yes. That's Doug's presentation, I think.

John Halamka – Harvard Medical School – Chief Information Officer
There we go. That is Arien's presentation.

Arien Malec – RelayHealth – VP, Product Management
Excellent. I'm going to skip through the first few sections, which now we're giving away all Doug's stuff, which essentially are an update on the projects or an overview on the project, just to remind everybody that the project is a project create specifications and services that need to be enabled within a policy framework and that are focused on simple, direct, routed, scalable transport over the Internet for secure and meaningful exchange between known participants in support of meaningful use. That's a mouthful, but it really highlights the fact that we're trying to take on a very, very focused project following on the observation of the standards committee's implementation workgroup, which in a hearing, I guess, a year ago noted that there are significant obstacles, particularly in smaller practices, to achievement of at least some of the meaningful use criteria because the lingua fronca of health information is paper, fax, courier. And that as we want to enable quality, as we want to enable information liquidity, as for example we need to have EHRs that can both generate quality measures and, I think, even more importantly, help facilitate decision support, that in fact is incredibly difficult to do if the information is captured in paper.

In particular, between many of the stage one meaningful use, particularly the menu set criteria for incorporation of electronic labs, for continuity of care and transitions of care, reporting of immunization records, you could go on, requires some form of a transport between settings of care or between a setting of care and some kind of institutional setting. And that there were significant obstacles to that activity, and that I think the third observation was that something that was simple and focused, and had a simpler set of policy requirements or policy implications, may do the nation a good deal of good by providing a simple, obvious path for directed exchange.

As everyone knows, in parallel, the various workgroups of the HIT policy committee and, in particular, the privacy and security tiger team has been doing really, really fabulous work in defining some of the key policy assumptions and policy guidelines related to directed exchange. And it's been good to see good alignment on the technology and the policy side. Go to the next slide. I'm going to skip through a bunch of these. How about the next one?

Early on, we started this project in March. One of the first things that we did was just essentially walk around, literally walk around—we were at HIMSS—to many of the organizations that are involved in health information technology. And asked them a pretty simple question, which was, would you like to participate with us in creating an interactive, iterative process to define these specifications with the understanding that once you do so, we will ask you to implement those specifications in early, real world implementation to test out all the work that we're doing. We felt that that process was very important by driving engagement and by driving ownership of the decisions that we were making in the specification process itself.

We were really extraordinarily – that's the wrong way of putting it. We got a ton of enthusiastic participation to the extent that we keep – we're having a hard time actually keeping track of all the organizations that are engaged in the project, and it's hard to fit them all on one slide. I think what we can say, if you look over this list, is that we've got a really healthy mix of many of the leading EHR HIT

vendors, many of the leading HIE technology vendors, as well as a good mix of public/private organizations such as regional health information organizations, state level health information organizations, national organizations that are currently providing information services, and the like. And I have been incredibly privileged to work with the team that has volunteered for this effort, and I've personally learned just a ton from all of these organizations.

The work that we're doing fits in a much wider context, so we're working on specification development activity and real world implementation activity. We recognize that there's a whole set of, as I mentioned, policy activities that are taking place in parallel, which at times has been slightly difficult. I think we've now got a really strong, very good working relationship between the Direct project and the tiger team where it's been extraordinarily helpful to have the tiger team essentially work ahead of us and provide appropriate policy context and policy guidance. And I think the dialog that we've had around the intersection between policy and technology has helped us in the project make, in many cases, revived many of the technology decisions that we've been making.

We do intend when this project winds down with a set of draft specifications, which we hope to be able to announce next month, and I think it would be lovely to come back to the standards committee a month from now and announce where we are. We intend to transition the specification work that we're doing to a standards development organization. There may be actually two standards development organizations that we transition off to. But we're kind of in flight on working at the logistics there.

At the same time, we're gearing up towards initial pilot implementations. We'll go, as you'll see in a second, a healthy set of initial pilot implementations, many of which are expected to do testing in November, and spin up their first provider connections in December of this year. Again, I can't say how helpful it's been to have the initial tiger team or the initial HIT policy committee recommendations come out of the tiger team and be endorsed by the policy committee to provide appropriate policy coverage and policy recommendations that are informing policy decisions for those pilots.

If we look at where this fits in the overall regulatory timeframe, as many people know, there's a set of governance activities that are taking place, again, in context of the HIT Policy Committee. And many of the governance, many of the policy issues that we're working through in the real world of implementation pilot, we expect to provide, A, learn from the work that the governance workgroup is doing, and then provide feedback to the overall governance process. And I'll return to this entire topic at the end of this presentation.

As I mentioned, we've got a set of implementation pilots that are taking place or in the late stage planning stages. And one of the interesting things is that each of these implementation pilots is focusing on key aspects of meaningful use measures. For example, the Med Allied pilot in New York, the RIQI pilot in Rhode Island, the work that's being done in California are focused primarily on providing continuity of care and transitions of care and, in many cases, providing closed loop referrals, closed loop transitions of care using directed exchange.

RIQI is going one step farther than that as well by, A, concentrating on closed loop referrals and continuity of care and transitions of care, and using the same direct standards to fulfill a larger term quality need for the state of Rhode Island by enabling the push of data to the RIQI quality registry in support of the beacon community, which I think is an interesting exercise in recognizing that the same push specifications can be used both for exchange of data between two covered entities in support of meaningful use, as well as enable, with a different set of policy frameworks, enable the push of data to a quality registry for long-term longitudinal analysis and quality improvement.

In the Vision Share pilot, Vision Share is working on connecting providers with a set of immunization registries. The first two immunization registries that they're working on are Minnesota and Oklahoma, and they're putting in place an adapter between the CDC PHN MS system, which those two states have implemented for their immunization registries, and the Direct specification, which again provides an

interesting lesson in the notion of adopting uniform transport standards, but then having adapters for those transport standards to meet organizations where they are. As I think many people know, the state of immunization registries around the state is varied and uneven, and it's useful to have organizations that can provide some uniformity to providers and HIT systems, and then yet meet the diverse set of needs that immunization registries have. The California pilot also plans to do similar work within a very different context where California has a flat file format for immunization data, publication to immunization registry that can do a pretty expansive set of things. And again, we're going to need to map the transport standards and the content standards that are in the final rule to the particular needs of the immunization registry across the state.

In CareSpark, the CareSpark pilot in Tennessee, we're actually looking at coordination of care for what VA calls the fee basis services. There's a whole set of care that veterans receive in the community. And order tracking for fee base of services is a really critical topic for providing quality care for veterans and requires good coordination across not only settings of care, but very different institutional models. And so, in this pilot, we're looking at the workflow that is informing those transitions of care.

One observation that I'll make is that although we started with the focus on transport, in the context of these pilots, we're actually wandering into areas that involve, how do you actually plug that transport into context, standards, and specifications? How do you integrate the transport specifications with elegant provider workflow? And I think we're learning a lot about how to do that in the context of these pilots.

What have we learned out of the Direct project? I'll talk about positive lessons, and I'll talk about negative lessons or improvement lessons. The positive lessons we learned is that if you can define a well defined, concrete set of outcomes that you're trying to achieve, and enable a process for focused problem solving around that business case, you can drive an amazing amount of engagement. I just can't say enough how proud I am to be part of the Direct project team, how much incredible work goes on at the workgroup level in the Direct project that we've got an enormous amount of energy and engagement in the process, primarily because we've been able to go heads down and focus on a particular business case that was identified as an obstacle to achievement of meaningful use goals.

We had a strong focus mission, and that strong focus mission drove an enormous amount of engagement. Asking for commitments, implementation, and pilots drives positive behavior and focus. And this was also one of the key lessons from the implementation workgroup hearing, as I said, a year ago, that if you look at the standards efforts and the specifications efforts that worked in other industries, you tended to see a very similar pattern of focused engagement around solving a particular business problem with a set of organizations that were committed to driving it out in the real world.

The third point is that the policy tools at ONC's disposal will work to engage industry broadly. What I mean by this is ONC has, and obviously everyone focuses on the regulatory aspect of ONC's work, but there's a much wider set of policy tools that ONC has at its disposal, and that the opportunity to align across all of the different ONC efforts and treat government as a platform, as well as not merely as a regulatory, as a source of regulatory authority, helps drive much more value than the sum of the individual parts.

Open source reference implementations are a key tool to promote standards adoption. One of the things we've seen in the development, for example, of the Internet is that high quality reference implementations end up lowering the total cost to achieve the value chain of interoperability, and we decided to take on, in this project, the work of publishing actually two high quality reference implementations. We'll talk about that in just a second. Then the last point is that communities are really, really amazing things. We can drive an enormous amount of – we get so much energy. We get so much enthusiasm. We get so much intelligence out of the community that's been created around the Direct project that it's just, as I said, it's humbling, and it's hard for me to explain how wonderful it is to, every week, have a set of workgroups that are going off and solving problems in incredibly creative ways that doesn't require a ton of top-down coordination or command and control.

Some things that, having done this, we would do a better job at, the implementation group, I think, so first of all, I just want to say, again, how amazing it is to work with the implementation group and how important it is to have all of those organizations participating in the process. I'd also say that when I started the work, I thought I was setting the burrier pretty high and hoped to get 8 or 12 organizations participating, and we got 70. That created a pretty huge scaling challenge of how to coordinate all of those organizations and drive energy and then drive consensus across all of those organizations.

In the future, we may want to set the commitment bar even higher and have some upper limits on the number of participants, not in the sense that we want to limit participation in the tools that can be used for broad participation with the public, but more the sense that the people who are doing the coding, implementation, specification development, and all that work. It's useful to have a smaller, more focused set of participants. It's easier to get to, for example, consensus in that group and move quickly.

Speaking of that, one of the things that worked really well was driving to code. We had a lot of discussion on use cases, on alternatives to specifications, on a lot of really important topics, but driving to code and driving to pilot have been two really focusing activities that helped clarify a lot of the theoretical discussion. And so if I had to do it all over again, I would have gone to code, and would have driven to pilot earlier in the process. And I think, getting to code earlier would have helped us to get to pilot earlier.

The third lesson, which I'm not sure that can be solved within a project like Direct, is that there are some fundamental philosophical splits in the HIT standards world, and one of them that I'll focus on is quality first or liquidity first. And that sounds like a funny dichotomy, but what I've seen and what we've worked through a good deal in the Direct project and then in explaining the work of the direct project to other HIT standards champions is that, in some cases, you've got a choice. You've got a choice between setting high bars for content, high bars for content metadata, high bars for technology in ways that you believe will drive to greater ability for organizations to accept the transactions and data that you're giving those organizations and do interesting things with it, and driving higher participation and higher data liquidity among a broader group of providers.

As everyone knows, we've got a whole set of providers who are not yet, have not yet adopted EHR technology, are in the process of adopting EHR technology, and yet many of those same providers have needs to exchange information with a diverse group of settings of care. And so one of the things that we solved for in the Direct project was how do you engage providers who may not have the technology means to create sophisticated transactions. And that ended up driving a lot of, as I said, philosophical discussions about, if you don't have all of the content metadata, if you don't have all of the sets of identifiers that organizations, that large organizations that have driven substantial quality are expecting to receive, how can they deal with that? Again, we go back to the observation that in many cases all of these transactions are taking place anyway. They're taking place via paper and fax and other kinds of mechanisms. And those large organizations are having to solve the same problems in any case.

I don't mean to belabor that particular point, but we've seen a lot of shifts and schisms inside the HIT standards world have some flavor of make it really simple. Drive the broadest amount of engagement. Drive the broadest amount of liquidity. Then that liquidity will drive the demand for higher and higher quality or a flavor of set the bar relatively high. Let's get a bunch of organizations up to that high bar of quality, and then we'll drive higher and more rapid quality.

We took the approach in the Direct project at the end that was a both/and approach, and that leads into the last point, which is that consensus is challenging when you've got fundamental philosophical splits, and you've got not just fundamental philosophical splits. You've got wide variation in the ability of U.S. healthcare settings to adopt HIT. So we've got a huge variation between the Mayos of the world and the individual, single doc physician practices that have a practice management system and are thinking now about adopting EHR. And driving to consensus that solves for all of those businesses is incredibly challenging.

And when you do that, you've got – as I think many people know, we had our moment of crisis where we had to solve and come to consensus in that context. And we had really two choices. One choice was to trust the community and let the community kind of work out the consensus and accept and embrace what we got, or we could have, and maybe should have, established an independent trusted review board, established some check on the community to make sure that the consensus that we're picking was the best overall consensus or the best overall approach for the HIT needs that we're trying to solve for.

What I'll do is talk for a little bit about the trust the community option. We had a set of findings, and I put findings advisedly in quotes because we didn't formalize the findings, but we drove to a number of conclusions. Number one is, even in the same transaction, you need to support structured and unstructured content. There are a lot of transitions in care cases, for example, where you want to be able to provide a structured document like a CCD or C32, but there's a lot of unstructured content like a textual note, like a PDF document, like a scanned image that informs that same transition of care. And, in many cases, you need to carry both structured and unstructured content in the same transaction.

We had XDR, which is the IHE specification for push transactions. It's actually based on the XDS registry repository model. Given a lot of the standardization work, given HITSP, given ONC, given the Nationwide Health Information Network, we'd seen good adoption and support in many modern EHRs, and so we actually saw a strong community of EHRs that had a preference for building on that technology stack.

We also learned during the process, given the feedback from the HIT Standards Committee review team, as well as the policy committee, that that transaction needed modifications to separate transport metadata from content metadata. That is that in order to figure out where the package of data needed to go to, you needed to reach into a set of content metadata that had things like patient identifiers, patient demographic information, what kind of transaction this was that wasn't strictly needed to get the package from point A to point B. And there was a desire to minimize and, indeed, a set of recommendations from the policy committee to minimize data access to just that that's required to complete the transaction.

On a simple point, XDR and a related standard called XDM have strong support for comprehensive content packaging. I'm going to make a distinction between the metadata that's available in the content standard itself, so for example a CCD has a strong amount of data and metadata about the package data that it's carrying. XDR and XDM have content packaging metadata that say, this thing is a CCD. It relates to this patient. Here's the clinical context under which it was produced. What that does is give organizations some uniformity in terms of handling content of varying kinds. You can stick a PDF. You can stick a CCD. You can stick structured and unstructured data into the same content metadata package and still give guidance to organizations receiving that package about what to do with it.

But there's actually a pretty high bar to be able to create that package level metadata, and we couldn't expect the broadest range of providers to produce that level of packaging. Again, this goes back into the philosophical debate between setting the bar high and getting providers to get to that high bar or driving towards the broadest range of interoperability. Really, in the philosophy of the Direct project, as I said, we did a little bit of both/and. We wanted to make sure that we had the broadest range of participation, and we wanted to make sure that there was an upward path towards more structured content package metadata, which led to the conclusion that we need something more ubiquitous to support the broadest community of providers, and there was strong support for use of SMTP or use of Web apps at the edge as a way of lowering the threshold for providers to participate in exchange.

Then, finally, and we could spend hours on this particular topic, the trust model that we were looking at required a relatively sophisticated approach to encryption and signatures, and I'll spend just a tiny bit of time talking about this point. If you have a centralized trust model and centralized enforcement of that trust model, as occurs in the Nationwide Health Information Network Exchange model where you've got a single certificate authority, a single directory that underlies transaction or a single authority for

onboarding, you can drive a much simpler set of trust enforcement because you've got, as I said, a strong central authority that can insure that all participants adhere to a common level of trust.

If we're trying to enable wide scale adoption and use of directed transport in a U.S. healthcare system that's diffuse, that's decentralized, we believe that we needed support for a trust model that allowed for organizations to start at a community level and then grow up to a state or to a nationwide level. That meant that we believed that we would need different circles of trust and the need to interoperate between those circles of trust. As I said, we could spend hours on this particular topic, but we came to the conclusion that what's called mutual TLS was not sufficient to enforce the trust model. That we really needed a way to encrypt a piece of content in such a way that the receiver of that content could verify, A, that it came. It was intended for them. And, B, that the receiver both is who the receiver is who he or she claims to be, and is in a common mutual trust circle to meet the same preconditions for identity assurance and authorization that the receiver has. Because of that, we need a set of relatively sophisticated approach to encryption signatures.

What do we do? What do we do with all that? We had a choice of three alternatives. We could use XDR, a SOAP transaction as the backbone, and use SMTP and XDR at the edge. That would allow for essentially leveraging the investment that many EHRs and NHIE vendors had already made in XDS. It didn't provide the same kinds of capabilities for managing distributed trust. There is a specification that allows for distributed trust and encryption and signatures. But it actually reaches pretty far into the WS security stack in ways that at least I wasn't confident had broad scale adoptability.

We could use REST as the backbone with REST, SMTP, and XDR at the edge. And that was indeed the recommendation that the HIT Standards Committee evaluation committee had given us. In that case, REST and the backbone would also use what's called SMIME to do the encryption and signature. Or we could use SMTP as the backbone and SMTP and XDR at the edge. Again, SMTP as the backbone would also involve the use of SMIME based content encryption and signatures.

It took a long time. The community came down to using SMTP as the backbone, but allowing for XDR end-to-end if there was known support and a trust model that supported that end-to-end transaction. Then SMTP and XDR at the edge.

The question is, does this represent the geneous of the "and"? Is this an "and" that's more than the constituent parts? Is it a triumph of the community? Or is it a mushy middle and designed by committee? If you go on to the next couple of slides, I think one thing that we've seen is that at least on a level of engagement, we've seen the ability to get to consensus on something that recognized the key care-abouts and key starting positions of each of the organizations that are part of the project has driven a substantial amount of commitment.

If you look at the wiki edit metric there, you'll see that we had our consensus meeting in July. We had a kind of drop off in terms of edits on the wiki. And then we came back from vacation, rested, energized, and we've seen actually more energy, more content created into the project after the consensus process than we did beforehand. If you stay on the left, we have an open source code repository that's been growing high quality code at a pretty phenomenal rate since July and August, driving in just a couple or few months to a really substantial set of reference implementations that you can take out of the box and implement the Direct specifications on. Then we've seen fuzzier models of engagement like energy and calls, active planning for pilots that again is qualitatively different than it was prior to the consensus approach, and just shows a lot of engagement, a lot of energy.

We saw on Monday some significant announcements on adoption of Direct standards. We're seeing specifications built into EHRs, HIE products and services. We're seeing states incorporating Direct specifications into state plans. Then, as I mentioned, we're seeing really interesting tests at both the SMTP and the XDR backbones in concrete implementation pilots.

In conclusion, I'm going to stand by our decision to trust the community. I think the wisdom of the community was actually pretty wise. And I think we could walk through each of the decisions that were made in that consensus and help people understand exactly why they were made and what they bring us.

What I'm going to do here is I've heard a number of common objections to where we came out that I just wanted to throw on the table and talk about. One is the choice of SMTP is a step backwards from structured content and HITSP endorsed standards. We've heard this a bunch. Just two points: number one is pointing out that both SMTP and … transport can carry both structured and unstructured data. That is, the transport that you use means nothing about the content standards that you use. And both transactions can carry highly structured content.

There's a belief that SMTP equals e-mail equals people writing text documents, and we want to support that model because we wanted to make sure that this was available to the widest set of providers, but we're not losing sight of the need for those transactions also to carry highly structured data like HL-7 version 2.0 transactions, HL-7 versus 3.0 transactions, CCD, CCR, and the like. The second point is that HITSP has actually endorsed XDR and XDM, and XDM can be carried over SMTP, and we made sure that in our endorsement of SMTP, we're actually recommending that if you can, you implement complex, the set of content packaging that XDM and XDR provides.

The second point that we've heard is SMTP means e-mail means spam means identity spoofing means privacy risk. Again, SMIME is a mechanism for content encryption and signature such that when I send a transaction, I have confidence that if I trust the certificate issue or I have confidence that only the recipient or a delegate of the recipient can even see what that content is. Anybody else is going to see a string of bytes. Then, as a recipient, I have confidence that I know the transaction came from where it said it did, and that we have mutual trust in the identity assurance and security in that transaction.

The third point that I've heard is distribution is a hard problem, and I'd say yes. It is a very hard problem. But unless you go to a centralized trust model, it's actually very difficult to get away from a certificate distribution problem. We're mitigating that risk through DNS distribution and through what we're calling the HISP architecture, which allows for a provider to delegate some responsibility for encryption and signature to a HISP, to an exchange in the short term. We believe that there's the national strategy for digital identity. There is the work the DEA is doing around scheduled medications. We believe that there are drivers to incorporating more use of digital identity and certificates that will eventually allow individual providers to control, hold, and manage their own digital identities and take responsibility for content encryption and signature verification. But in the meantime, we believe that the approach that we came up with allows for reasonable scale of encryption and verification.

I will pause there. I think we've got— I don't know, Doug, if you want to go first, or if you want to take questions first.

John Halamka – Harvard Medical School – Chief Information Officer

Why don't we take some questions at this point? Let me just take us back, Arien, a year when we all sat around this table and said there are three ways you can send data from point A to point B. There's SOAP. That's great because it's trusted by the government. It has wonderful security layers. It has NHIN Exchange implementation. But as you say, it doesn't apply a certain amount of programmer development overhead, and how many people are there in the world that know the entire security stack and can implement SOAP quickly? Well, it didn't seem that that was the most direct or easiest approach, although many thought it was a very functional approach.

Then there was REST. Come on. Facebook, Amazon, Twitter, everyone can do REST. In fact, my 17-year-old daughter can do it in an hour in her sleep, and how simple it is. But then there were questions about how can you control the security and integrity of the message, and is there anything really in the REST standard because isn't so much a standard as it is an approach, that would enable a set of tools

that would allow you a lot of the controls that SOAP provide? Maybe they had to be proprietary development, new tools layered on top of the REST approach.

Then SMTP, easy, simple, ubiquitous. However, it is asynchronous. It doesn't have that AC/NAC kind of approach where you know immediately that you've achieved the message delivery. That certificate management, that's pretty challenging.

That's where we were a year ago, and you have succeeded in going through these. I'll tell you, as I introduced your comments probably before you were on the phone, I actually thought REST was going to be a winner. And REST is the one transaction you're not supporting at all. Any comments you would make on some of those pros, cons, and the fact that REST just disappeared? SureScripts, by the way, happens to use REST successfully. What about Facebook?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes. As I think many people know, I've not been shy in promoting the REST approach myself. I would say that if we measure the success of a standard or specification by how much enthusiasm and energy there is to implement it, we had much more engagement and enthusiasm in a pretty representative group of HIT vendors and users for SMTP and for SOAP than we did for REST. REST was actually the one approach that had the least objection, but also had the least energy in the room.

The comments in favor of SMTP were twofold. Number one was the observation that reliable store and forward messaging is nationwide in scope is a solved problem. We've got all kinds of infrastructure and monitoring tools and operational data centers that support it. And it's all built on top of an SMTP infrastructure. The second comment is that SMIME as the content encryption and verification or digital signature approach is actually nicely embedded into an SMTP workflow and helps us drive potentially wider adoption in use than otherwise.

And I think the third piece of feedback that we got from organizations that were in the business of doing large-scale transactional support in the middle was, you know, at a transactional level, we can make all these things work. Actually, let's focus on what we need to do to engage providers and work out backwards. And what we needed to do to engage providers was, A, meet EHR vendors where they currently were, which was XDR and built on top of XDS. And at SMTP in terms of its ability to scale out to a broad set of providers, so that was the set of design criteria that went into the selection.

John Halamka – Harvard Medical School – Chief Information Officer
Marc Overhage.

Marc Overhage – Regenstrief – Director
Thanks, John. Thanks, Arien, for that nice overview. I actually have two questions, John, but I'm going to sneak them both in. The first is, and you just alluded to this. I'm a little surprised to see XDR appear 11 times in this document, and then the comment that you just made that many EHR vendors support it because that's certainly not our experience in the field. And I think you heard several people this morning. I'd love to hear people's comments about the EHRs that are out there. So I wondered if you might expand a bit on that assertion that XDR, SDR has implementation support in many EHRs. I guess I'm particularly interested in the EHRs that we're likely to find out there. That was the harder question.

The easy question, I think, is because I think the answer is pretty evident, and it's yes, is when you talk about the certificate distribution being a hard problem. I think I heard you say, but I just want to make sure I was clear, that the solution was a common trust model because the certificate distribution is problem is hard, and that the HISP architecture is a centralized trust model because there's no other near term solution.

Arien Malec – RelayHealth – VP, Product Management

I'll do the second question first and then go to the first question. We believe in the project, and we've had tons of discussion about this that policy is drastically and dramatically needed to enforce at least a minimal understanding or a floor understanding. Minimal is the wrong word. A floor understanding of strong trust models that encompass identity, that encompass privacy and security, that encompass transparency.

The work that the privacy and security tiger team and the HIT policy committee have been doing is, I think, absolutely and drastically needed. And the observation is that policymakers sometimes think of themselves as putting the breaks on. And, in many cases in this area actually, policy will help us accelerate information exchange at scale and at trust, and that policy is dramatically needed to help us get to ubiquitous nationwide scale. In the meantime, because the policy machinery is very strong, but sometimes not so fast, we need mechanisms that allow us to build regional trust circles and then mechanisms to allow organizations to say, you know, your policies, my policies have a common floor, so we're going to trust each other in ways that allow us to organically grow information exchange while we get to a common set of principles and understanding for nationwide trust.

Marc Overhage – Regenstrief – Director
I'll take that as a yes to the second question.

Arien Malec – RelayHealth – VP, Product Management
Yes. Sorry. Sometimes people who know me well know that yes/no answers don't come naturally to me, so I apologize for that. The first question, you know there's a huge difference between, I think everyone knows, there's a huge difference between the latest version of an EHR and what you see in the community. We got, if you look at the slide of implementation group participants and sort of count up all the EHR vendors who participated in the process, you'll see that most of or almost all of the leading EHR companies were in there, and they all had a preference for SOAP based transactions. And they'd done a proof of concept where they basically took their latest version and hooked them all together and gotten live orchestration of message flow between systems.

Now does that translate into right now the ecosystem for HIT in the community to support, sustain transactions? I think the answer is pretty obviously no. And so I guess that's what I'd point to is there's a significant difference between the latest version of EHR and where the EHRs in the community are. That's actually another reason that we wanted to make sure that we had something that was easy, low cost, and more ubiquitous to work on in the meantime, as we got to broader and more expansive adoption.

In many ways, if we got to a world where everyone uses SMTP or everyone uses SOAP, then that's great, and we'll narrow it down to one. But we did want to make sure that we could meet the EHR vendors where they were going, as well as meet providers where they currently are.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Along, I guess, the same track that Marc was going down, I too am sort of interested in a little bit more of the behind the scenes thinking on the XDR thing. Honestly, this was discussed to a very significant level, even a year ago, and as Marc says, I don't think we can think of it as "supported" at EHRs in the field. I just want to understand, and also separate the idea that if there's a preference for SOAP, that therefore means XDR. Those two are not necessarily married to each other.

I guess one other point of clarification, and I think it might have been John who said this that the security of something related to security wasn't doable with REST transactions. I hope we're not saying that … financial services and what have you, others that are using these kinds of transactions are not paying attention to security. I think there's – I just don't want to … how we got here, and just remind you that even if the XDR type standards are supported by "newer" products that may not be out in the field, they're unlikely the products that are going to service the very population of providers that this … was meant to deal with, the physicians in small office practice who are going to be using more lightweight, who we want

to be using more lightweight tools, and who we want to benefit from innovation. And I guess I just want to understand what's behind the thinking here.

Arien Malec – RelayHealth – VP, Product Management
Sure. I guess the observation that I made at some point during the course of discussion, when I heard EHR vendor after EHR vendor after EHR vendor stand up and say, we've got a preference for this, is that the easiest thing to support is the thing that you already support. Now that does create challenges for innovation, and I want to acknowledge that. But we've got such a strong and such a unanimous or close to unanimous set of feedback from the organizations that are currently out there providing products to providers that they had a strong preference of going in an XDR direction.

Now clearly we didn't go only that direction for many of the same reasons that you're suggesting. But I don't want to underemphasize how strong and close to unanimous that sentiment was. In terms of SOAP doesn't mean XDR and those kinds of things, as I said, the easiest thing to support is the thing that you already support, and those EHR vendors by and large already supported an XDR or XDS transaction that's mapped over very well to XDR.

A third thing that I didn't mention that I do want to make sure I am mentioning is that we took the privacy and security concerns to heart and have been working very closely with the implementers and with IHE to make sure that we are carefully separating out the transactional metadata, the where does, you know, who is this from, and who is to, from the content metadata such that organizations in the middle do not have to examine the content metadata in order to fulfill their minimum function of routing transactions from point A to point B. I guess the last thing that I'd want to point out is that we created in the reference implementations that we're creating, we're trying to create a set of common toolkits and APIs that EHR vendors can just check out and deploy in ways that allow them to use SMTP or XDR or XDM or any of these other things at a much simpler, much higher level of abstraction. So there's no obligation to use XDRs as your transaction. There's just recognition that there are many EHR vendors that already support that standard and were happy and ready and eager to build on that support.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Just a point of clarification on the metadata. Are you saying that the metadata is not in the registry?

Arien Malec – RelayHealth – VP, Product Management
XDR doesn't have a registry context. What I'm saying is that in order to move data from point A to point B, the organization in the middle that may be doing the switching all needs to look at the top most envelope that doesn't have in it the manifest file. I don't have to read the manifest of the package in order to understand that this needs to get delivered to Dr. Jones. So we've worked very hard to separate out the address label from the manifest from the actual package content so that organizations can minimize the amount of information they need to examine in order to minimally fulfill their exchange function.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
But does the receiver need to know that the receiver can support it?

Arien Malec – RelayHealth – VP, Product Management
Again, the XDR transaction is only used end-to-end if the sender and the receiver mutually know that they both support it, so there's no obligation that a receiver needs to be able to receive XDR. There is an obligation that a receiver needs to be able to receive SMTP. That is the common … background is SMTP.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I think therein lies the … because if the receiver doesn't support it, and the sender says, well, this is the way we send it, it kind of goes against many of the reasons that this whole undertaking went on. The idea that to support simple exchange, sender and receiver need to know nothing about what apps they're running at the edges.

Arien Malec – RelayHealth – VP, Product Management
Correct.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
But the sender can just drop it as a zip file and send it as an SMTP, so it in fact can be sent to anyone.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
If the sender says that they are willing to support that. If the sender says I'm only supporting the XDR, then you lose it.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes, but then they're not direct at that point.

Arien Malec – RelayHealth – VP, Product Management
That's right. I just want to be really clear. The common transport is SMTP, and you only send XDR if the sender and receiver both know that they can both support it. If you don't know, you send SMTP.

John Halamka – Harvard Medical School – Chief Information Officer
Right, and so the geneous of the and Arien that you described is the step up, step down function that if you choose to send XDR, it certainly could go over the backbone SMTP. In fact, minimally, SMTP must be supported as the backbone.

Arien Malec – RelayHealth – VP, Product Management
That's correct.

John Halamka – Harvard Medical School – Chief Information Officer
Then the receiver could receive it as SMTP, or if they wish, convert to XDR, but that's up to the receiver. There's no prerequisite that the receiver receive XDR. And, as you say, the only time that XDR would be used end-to-end is if by common agreement the sender and receiver had such a choice. In Massachusetts, our health information exchange doesn't use XDR. It actually uses SOAP. But what it does is we have agreed across 42 gateways that we're going to send SOAP one to another, and that's a pre-agreement. In that sense, it would be consistent with your – if there's a pre-agreement, you could.

Arien Malec – RelayHealth – VP, Product Management
Exactly.

John Halamka – Harvard Medical School – Chief Information Officer
But if it's truly NHIN Direct support and, of course, Massachusetts has every intent of supporting NHIN Direct because we think there'll be many endpoints that end up connecting that way, especially smaller practices, that it might start with a SOAP transaction from a larger organization, but certainly then would end in an SMTP transaction to a smaller organization. And that would be fine.

Arien Malec – RelayHealth – VP, Product Management
That's exactly right. You said it much better than I did.

John Halamka – Harvard Medical School – Chief Information Officer
The challenge, of course, is that as a committee, you've seen what has been, well, not quite a year, but probably in dog years, it must feel like a year, Arien—what do you think—of work that the consensus of this group, through significant amounts of governance and coding activity, has been a combination of approaches that supports both the big guy and the little guy. Enables the use of code that already exists, while also fostering innovation for new applications that don't yet exist. And I think a question for the committee is you, Arien, wanted to present this as, here's our work. What do you think? And are there

any other comments around the table? I see Dixie has her card. As to advice, consent, recommendations? Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Needless to say, I'm a bit disappointed that all of our recommendations were ignored, but aside from that, I'm encouraged by your last explanation, and I just want to make sure that I understand it, Arien. That is, we spoke about it, and our primary recommendation was that if a third party is implementing this, we wanted the services that are offered to be able to be split, and offered as separate services, so that if Dr. Baker is sending something to Dr. Halamka, and I want to send it just SMTP, and I want to make sure that the third party does not see the content for transforming it into XDR or for any other purpose, that I can go to that HIE, that third party, and say I only want my support for end-to-end SMTP. I don't want you ever to look at the content, and be able to get that.

Arien Malec – RelayHealth – VP, Product Management
Absolutely. The way that we've designed this is that you can make the decision. Dr. Baker can make the decision that she never wants her HISP to ever see unencrypted content. And Dr. Halamka can say, well, I'm actually going to outsource to NEHEN, and I really want them to manage that function, and the transaction will just work. That is, you can make independent decisions about the business arrangements that you have with your business associates that fall within, and this is where I really need to say, and fall within the HIT Policy Committee recommendations for that business arrangement. But you can make an independent decision about how you want to send that transaction and have absolute confidence that the party that you're contracting with can never see the data that you're sending except for the bare outer envelope data.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
And even if the other end has – let me make this clear. If the receiver then uses a service that does do the XDR translation, that's—

Arien Malec – RelayHealth – VP, Product Management
That's their business. Yes. That's a local decision that they have no right and no ability to make you conform to their heightened recommendations or requirements. And we've had a lot of discussion about, well, you've got providers in the community who can only send text, and you've got organizations that have lots of machinery around patient matching, patient identification, those kinds of things. We don't want to force individual providers to conform to the service levels of the largest providers, but we do actually want to provide an upward path that as the individual providers become more sophisticated in the technology that they've adopted, that they've got a good path to make sure that they get up to a level of sophistication where they may actually get faster information flow because they're able to supply more data and more metadata.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay. Thank you.

Arien Malec – RelayHealth – VP, Product Management
And I do want to say that we did not ignore the recommendations. In fact, we looked at the policy recommendations, as well as the technology recommendations, and that was a huge part of the decision. I want to thank everybody….

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It does sound like you listened. It sounds like you heard our – it sounds like it, at least, that you listened to our concern about the possible exposure and manipulation of health information, I think.

Arien Malec – RelayHealth – VP, Product Management
Yes.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I'm going to have to go and read a bit more about it, the part that I share John's disappointment that the rest of our REST recommendations was not….

John Halamka – Harvard Medical School – Chief Information Officer
Yes. Dixie, all that Arien can tell us is it had the fewest objections of anybody. It just had nobody who loved it.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I know lots of developers who love it.

John Halamka – Harvard Medical School – Chief Information Officer
Jamie?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. I'd like to, if we can, just take a look at the project plan page for a minute. And I wanted to reflect back that we heard about this project about six or seven months ago, and the goal that I think was stated at that time or one of the main goals was to have a number of real world implementations with real world providers in the September timeframe, and so I wanted to ask. And so what is the number of real world implementations with real world providers?

Arien Malec – RelayHealth – VP, Product Management
Thank you for that question. I would say very honestly that it's taken us a little longer than we had hoped in the project plan to get through the consensus and the specifications and figure some of this stuff out. We were thinking September, October. It's actually feeling more like you move that out a couple of months. It's feeling more like November for testing and December, early January for initial pilot implementation.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Is it correct then that it's actually not in production anywhere?

Arien Malec – RelayHealth – VP, Product Management
It's correct that it's not in production anywhere.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
So now looking at the project plan then, it shows on a regulatory activity line an evaluation by this committee now, and basically if there are no results, what are we supposed to evaluate?

Arien Malec – RelayHealth – VP, Product Management
Thank you for that as well. What I'd actually love to happen is essentially a two-phased evaluation or actually a three-phased evaluation. But I would love for this committee to look at both the specifications that we've developed and the reference implementation, and provide review and feedback. But I feel very strongly that the standards committee should be reviewing this work as a possible recommendation after we've proven ourselves in the sense of a real world pilot and, as we have an SDO transition strategy.

I guess what I'd ask is I think there's one ask that I have of the standards committee to do a reevaluation of where we came out along both the privacy and security lines, as well as the standards lines. And then do a secondary evaluation when we've demonstrated this in the real world, looked at what worked and what didn't, and put in place our SDO transition strategy.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I guess I would like to suggest that we should do the evaluation after we have an actual implementation to evaluate.

Arien Malec – RelayHealth – VP, Product Management
I'm fine with however the standards committee wants to work through that timeframe.

John Halamka – Harvard Medical School – Chief Information Officer
What do you think is that timeframe by which we would have the detailed specifications and an existent running organization so that we could evaluate the success of the approach?

Arien Malec – RelayHealth – VP, Product Management
Detailed specifications and finalized reference implementation by early next month or pretty close on both of them, and then implementations, as I said, starting late December or early January. Perhaps a good check-in point would be March in terms of having finalized specifications, finalized reference implementations, and field experience across multiple implementations.

John Halamka – Harvard Medical School – Chief Information Officer
That seems fair. I might imagine the privacy and security workgroup could take a look at your final published specifications to make comment, but then a committee wide evaluation in March. Jodi, you had a comment?

Jodi Daniel – ONC – Director Office of Policy & Research
Yes. I just wanted to ask then the connection with the review of this standards committee and then the next … on there, which is evaluation for inclusion by NHIN and what the role, just what those connection points and the role in this committee in any recommendations and how that would work.

Arien Malec – RelayHealth – VP, Product Management
Jodi, is that to me?

John Halamka – Harvard Medical School – Chief Information Officer
Arien, from your perspective, since you've worked with all of these stakeholders, dependency upon the federal advisory committee's approval and endorsement before or in parallel with your NHIN discussions since you have in your stacking diagram multiple entities doing multiple things … March evaluation dovetail into some of the other activities.

Arien Malec – RelayHealth – VP, Product Management
It's super complicated because we've obviously got governance activities that are taking place at the same time that we're doing this implementation work. There is one well-defined path that I'm sure Jodi could speak to way more authoritatively than I whereby the standards committee can make recommendations to the secretary, and the secretary has a defined process for evaluation of those recommendations. And what I don't know because the governance process is underway, is what's the governance process for, what's the going forward governance process for deciding new Nationwide Health Information Network specifications or standards.

There's an existing process to the technical and governance committee of the Nationwide Health Information Network that I'm actually not even sure has the same ONC recognized standards gateway. I'd have to talk to people who know much more about that then I do, which is a long explanation of saying, there are a lot of things happening at the same time. And I guess the request that I'd have is that we make sure that we're linking up all those activities appropriately to make sure that we're coming out on a timeline and a process that makes sense.

John Halamka – Harvard Medical School – Chief Information Officer
Let me ask Doug because your presentation, which will follow, will be about the S&I framework, which does include now a replacement for what used to be HITSP, what used to be the notion of the secretary looking through an accepting, and these sorts of processes will now have a new approach. And so a

question would be, given that NHIN Direct has been a project before the S&I framework, is it something we now plug into the S&I framework, how might we resolve all of these questions that Jodi has asked?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think when it comes to sort of approval or recognition of these things, I've got at least four, but there may be more. I don't know. There's the HIT Standards Committee recognition of these things as being appropriate to support some of the meaningful use requirements. We have the Nationwide Health Information Network recommending a particular specification for folks that want to use the exchange as a mechanism of doing that.

I think we also have to talk about standards development organizations and making sure that we are engaging them in this process as well. It's important from an OMB perspective as well to make sure that they're engaged in that process. Then there's sort of an OCN. Is this part of the portfolio of things that we want to put forward that will help with interoperability. I think, articulating that and figuring out what are the right pieces become really important.

When we go onto my slides, the reason that I wanted Arien to go first is because I want, within the committee here, to have deep knowledge of kind of what has worked and what maybe we need to work on in trying to figure out how we can get what has worked into the S&I framework, and what things we need to provide perhaps more governance or some ways of coordinating. How do we do that in the right way? I don't have in my slides the solution, but part of it is to tee up what some of those issues are and then have a discussion within this group to make sure that we find the correct angle of repose, if you will, between the top down and the bottom up mechanisms of coordination.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I was, of course, active at the start of this, and have not been that active since then, so I feel a little bit like the deadbeat dad here. A couple of points I want to make, harking back to the original report of the implementation committee, the idea is to focus on getting something done short term. If in fact the project has live data running in multiple communities less than a year after it physically formed, that will be a new land speed record, I think. So I'm not trying to prejudge the ability to do it, but I am saying that we should look at, if it lives up to that goal, we should look at it as a dramatic success.

Second, I think we need to be clear on what the levers that are available to ONC we advise in this regard the current posture, regulatory posture that ONC has taken is to certify systems for specific means of interoperability, evaluate meaningful use based on the success of achieving interoperability in at least a few cases, and a growing number of cases, we assume, but not to evaluate systems for meaningful use based on their using the standards that are in the regulation for certification. God forbid it should be the other way because there are a bunch of lab interfaces that have to be redone in order to get the meaningful use incentives. To the extent that that posture continues to be the same for the 2013 regulations, we need to judge this effort based on adoption and proven record for ramping up and not ask the question, are we going to disallow it. That is, I don't know that there's a policy lever to disallow a form of communication providing that it meets the areas that there are levers for, such as HIPAA requirements and state requirements and things like that. So I think the best outcome is to find that this has demonstrated that it's working well enough to begin certifying for it. Therefore, increasing the ease of adoption.

The worst outcome would be to say, you know, people are using this, but we don't like it. Let's stop it. And I think we need to work within those parameters.

John Halamka – Harvard Medical School – Chief Information Officer
The timing, luckily, if we're going to look at a March, which is relatively soon, timeframe, and we don't have running implementations yet, we hopefully will get a thorough review that will dovetail into the cascade of other events in a timely way. It seems to me that this is a national coordination of efforts that might need to take place. And so I would suggest, if we all agree, that we will get your specifications,

Arien, as soon as you think they are ready for the privacy and security workgroup to review, and then as a collected committee, we will plan for a March thorough review based on the actual implementation. Then, as Wes has said, we don't want to get into a situation where the whole industry is moving in this direction, and we saw no. Hopefully this compressed timeframe we've just suggested will allow this to flow in a linear way. Other comments? Jim?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Arien, if I understood you, you were asking for a formative assessment from the committee prior to a summative assessment later on. It seems to me that that's good project management, and it sounds like the privacy workgroup is going to be provide you some of that summative assessment. I would just say that it's, granted my ignorance of all of this, it sounds like the process was well done, like you have really done a good job of understanding the community of people who would need to execute this, and that while you have not unnecessarily furthered the positions that the standards committee took, it sounds to me like you have furthered the interests that the standards committee was trying to suggest with its positions.

Arien Malec – RelayHealth – VP, Product Management
I certainly hope so.

John Halamka – Harvard Medical School – Chief Information Officer
Any other comments before we move on to Doug's presentation? Thanks, Arien. We certainly look forward to getting further information and working with the group. Now to introduce Doug's presentation, Doug, before you got here, what I had suggested was we all, in discussing the NIEM approach and the S&I framework, recognize there are certain tasks that go from use cases to running code and testing, and that NIEM as something that has worked quite well in a homeland security context and is being used by other branches of government, but of course there was some concern raised in the industry that NIEM implied a variety of actual bits of XML and standards and something that would be related to homeland security. And in your presentation today, we will review some of the structures and the processes. I have noticed that the word NIEM doesn't specifically appear. I think the committee would feel quite comfortable if you said here are the things we are going to do, and we're going to inherit all these lessons learned that have been had in NIEM processes, and we are going to adapt them for healthcare in our own unique way, taking the best without some of maybe that worrisome baggage that others in the past may have voiced concerns about, so look forward to your presentation.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I just want to thank Arien for all the tremendous work that he has done. He has worked tirelessly on these activities and has done a tremendous job in sort of moving things forward and giving us a lot of information with regard to the Direct project and how to move forward. I'm going to start with this slide because I'm beginning to start all of my slides with this slide, which is to talk a little bit about the standards and interoperability framework and how we can get to what the implementation workgroup had sort of talked about with regard to this notion of focused collaboration.

When we think about organizing the standards and interoperability framework, there's sort of two ways that we can do this. We can do this in sort of a thousand flowers blooming and having lots of different projects that are trying to solve specific issues in which we can get good engagement from the participants, but perhaps not focused broadly across all of those solutions towards things that fit into a sort of strategy, if you will, for achieving interoperability. The other way is you can take a command and control, top down where we clearly articulate where it is that we want people to focus on. But in those situations, people don't necessarily own the project, or they don't necessarily own the result. And, as a result, the participation is less.

We really want to have this notion of being able to prioritize things that provide value, create processes that are transparent and that people can engage in directly, and that we can rapidly iterate and produce results. And so one of the things that we believe or is that a hypothesis out there is that the Direct

project, if we compare that with some of the interoperability framework, we may be able to achieve that sort of focused collaboration. I have just repeated the NHIN lessons learned here just to sort of emphasize those again.

I think one of the things that have been helpful is solving specific problems around a particular use case. I don't mean that in the sense that the standards development organization does that, and then the implementation specification group does that, and then the reference implementation. But in fact, the Direct project looked at the entire value chain all the way from the beginning of the project, all the way to the end. And I think that becomes something that I think is really an important aspect of what we need to look at.

What I'd like to do when I think about the standards and interoperability framework, I know that we've talked a lot about it here, and I know that I think about it a lot in terms of how to organize it with all of the various moving parts, but ultimately I don't want it to be about the standards and interoperability framework. I don't want that to be the focus. I want our focus to be on kind of the national goals that we have within meaningful use: quality, cost, access, public health. I think that's what should drive what happens down below.

That means that to support those national goals, we want to be able to have robust interoperability across settings of care. The ability to sort of increase the systemness of care delivery that we've got kind of embedded in the care delivery process. The ability for the various systems to sort of work together, and realize that we're really talking about an ultra large scale system with lots of moving parts that have different parts that are going to be in different levels of sophistication. I mean, we're going to be having some parts that are going to be replaced and upgraded at the same time that other folks are going to be working in different transactions or the like. And so we want all of the priorities that we work on, the next set of projects or next set of goals, to sort of support those national goals to create that robust interoperability and then have the standards and interoperability framework used to support that work. It becomes the how not the what. I think that's important for us to sort of think about.

One of the things that I struggle with or that I keep trying to figure out, and I want to learn as much as I can from the Direct project and from other sorts of standards development and standards coordination mechanisms. If we're going to make mistakes in the standards and interoperability framework, I want them to be unique. I want us to learn what we can from other experiences and let's make sure that what we do are successes in things we can share, but let's make sure that we don't create problems that have already been looked at.

When I think about moving forward, there are two ways that I think about coordinating this group. I can do it by saying let's pick very clear problems that we want to solve. Let me just – we haven't necessarily decided what those are, and I think we need to have input from the policy committee and from the standards committee, which is why I've listed their priority one, two, three, and four, rather than putting up any sort of straw man or straw cases that we might consider. But let's just take one, say, like laboratory interfaces. If what our target is to reduce the cost of developing a laboratory interface by 90%, let's make it an audacious goal that we want to hit. What that means is that I need to have every piece along that value chain respond to that.

My big fear in the standards and interoperability framework is that I will have a standards development organization that says we've developed our standard. It's great. We did it on time and under budget, and there it is. And I'll have my implementation, but the standard will not have been tested. We won't know if it actually solves the use case, but we've met our milestone and we've got it in place.

And then my implementation specification group will develop the implementation specification, and they'll do it on time and under budget. But it will have to be pointing to two different HIE specifications and four different other standards development organizations, but with links because we haven't kind of worked

out the IP. And everybody will look at that in that Word document, and they'll say, this is a great specification, but I'm not quite sure how to implement it.

Then my software developer folks who are developing the reference implementation will take all that information, and they will actually develop a piece of working code, and they will do it on time and under budget. But it will have 50 different configuration switches that have to be configured. I'll have all sorts of complexity in which environments it can work at. And so what I'll have is I'll have an S&I framework in which everybody will be green across the board in terms of project management, but we won't achieve the national goal of reducing the cost of a laboratory interface by 90%.

And so, if I'm trying to kind of coordinate across this, there are two ways that I can do that. In fact, I probably need to use both mechanisms. One is to make sure that we have focused goals that we're trying to achieve because, if you have focused goals, it makes it easy. If you have A and B that you're trying to choose between, and A gets you to the goal, but B doesn't, it becomes easy to kind of make those decisions.

But across these priorities, we probably need some coordination because they may have different goals, and so we need to also have sort of a committee structure or an approval process or some other mechanism to make all of that happen. But if I can organize the standards and interoperability framework around setting very specific priorities that drive to value across the entire value and sort of food chain, and then I use the standards and interoperability framework, not as an entity in and of itself, but as a supporting structure. Again, we've talked about government as a platform, but as a supporting structure to make sure that people are successful in achieving those goals for priority one, two, and three. I can make this not about the standards and interoperability framework, but I can make it about those higher level goals that we have with regard to sort of driving for value and making sure that we're sort of hitting those targets because, at the end of the day, I would much rather just miss the mark on one of these high priority items than I would to have my entire standards and interoperability framework green and not actually even come close to sort of those national goals.

And so what I sort of, and the reason I wanted Arien to go first is that we had one example of sort of focused on a very specific problem and trying to sort of support that. If I had a whole bunch of those in flight that people were working on, and every couple months we launched something that we thought was important, that we got input from the policy committee and from the standards committee that we thought that these were things that we needed to work on, I can then organize my various contractors in the S&I framework to help support that. And it may be that we need to have people who are on these various teams that represent the SDOs. Get them involved early. We've got other people that may not be part of that standards and interoperability framework that need to come to the table. But we use that as a way of leveraging the various priorities.

The things that I would welcome some discussion on and to sort of think through, given what we know now about the NHIN Direct project, not so much even in terms of what kind of consensus they came to, but in terms of the process that they followed. And there are issues about kind of trusting the community to come out at the end of the day with something that will work, but also making sure that you have the ability that if we get ourselves way off track in terms of where all of these pieces fit to be able to have kind of committees like this to be able to provide input and advice. But I think one of the things is I think if we organize the standards and interoperability framework about solving these problems so that we have clear, demonstrable targets. I can use that as the glue for how all of these pieces will fit together. I'm still going to need some other kinds of structure, and I think input from the governance working group and from this committee I think is going to be helpful.

I can then have each of the team members within the S&I framework work at the appropriate place. So we didn't have the S&I framework in place when we started the NHIN Direct project, but one can imagine that as the wiki and the discussion is occurring, I have Accenture translate that into a standardized UML representation that I can then put into my databases of information. Then, as we get to the point where

we're coming up with those specifications and we're thinking about an implementation specification, I can then use my harmonization and implementation specification team to translate that into a standard representation, again, that then goes back to that kind of priority group and says, did we get it right. Did we translate that into – did we capture everything you thought was important in this process? It gives me some quality control, and it gives me a way of sort of focusing the work of the various folks.

It then allows me to operationalize the processes and problems with metrics, risks, and milestones based on what those projects and those initiatives feel are important. And I hope, if we keep the scope appropriate, we can solve these problems in increments. We've got then this kind of gradually building set of resources that can be used to increment version two and version three of a particular initiative. And I hope, as we go forward, we can balance between sort of the bottom up and the kind of goal directed coordination around these targets and sort of a top down structure of coordination that may require some committees and approval and other things like that.

I wanted to take the work that Arien has done and to frame it, as we think about going forward within this S&I framework, and to have some discussion and comments from the committee as to whether this is a reasonable strategy, whether I need to rethink this. I am working right now with my team to come up with an update to … that was relatively high level that we shared before where we're drilling down to see really how is this going to work and what is the kind of structures that we need in place so that we can be successful. But I really want to make sure that we, at the end of the day, hang out there a little bit with some audacious goals that we may not necessarily have complete control over, and not necessarily hold back and say, everybody is green. Therefore, our project is a success. But, at the end of the day, we actually don't advance the national agenda and the things that we're trying to do with regard to national care, quality, and coordination.

With that, I'm going to stop, and I'm going to ask you guys. I'm the only thing, I think, standing between you, public comment, and lunch, so I'll stop there.

John Halamka – Harvard Medical School – Chief Information Officer
Let me just – I have two quick comments for you, which is, both you and Arien asked do you trust the community. I think the answer is it depends on who is the community. If the only people who can afford to go to the meeting are well established constituents that are large organizations with lots of funding, then maybe the answer is the conclusion they come to may be a very good conclusion for that community, but it may not be the right answer for the broader community. I think if the answer is you assemble a community, but also have, as Arien suggested, an independent review of the output of that community, then you have the best of both worlds. It's both bottom up and top down. One hopes that the HIT Standards Committee, which does seem to represent quite a lot of … stakeholders, could serve as an independent review body of your success.

One of the things that we said earlier today was maybe not only do we need a process and outcomes measures, but we also want IT enablement measures. Well, just a quick story. I was recently asked to do two laboratory interfaces to two community health centers that have EHRs they have installed on their own with compendia they have built on their own. And I have budgeted about $50,000 per interface to deal with the VPM in all aspects of transport, compendium building, testing, validation, etc.

This is just a laboratory results interface. You should be able to do these things in a commodity fashion as easy as plugging in a USB. Well, maybe not quite that easy. And so if the IT enablement measure was, did Doug, through the S&I framework over the course of a three-year period reduce the average cost of a generic laboratory results interface from $50,000 to $5,000, I'd call you a hero. You too? Okay. Other comments? Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Thank you, Doug. I appreciate your comments, and I guess philosophically your principles are unimpeachable. You referenced ultra large-scale systems, which harkens back, as you know, to the IOM

sessions on interoperability. Among the questions that were raised in those sessions is who in the HIT standards world would emerge as the moral equivalent of the IETF. The IETF, for those of you that aren't familiar with it, is the Internet Engineering Task Force, the people that bring you the Web, the Internet, and all the micro standards on which it operates.

One of their principles, as you know, is they'll entertain no standards unless working prototypes with at least two adopted representations can be brought forward. Furthermore, they have an emphasis on parsimony that is to say, many standards are not good for you, but a small number of very core, well engineered, fundamental standards seem to do the trick for these ultra large-scale systems. If we acknowledge that healthcare and health IT in particular is arguably evolving toward an ultra large-scale system that would be in demand of these parsimonious interoperability standards, to what extent is the S&I framework, as you see it unfolding, able to point to, as I say, the equivalent of an IETF?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I don't think that the S&I framework is the IETF. But I think the principles that are part of the IETF, we will adopt no standard unless it's actually been used and used not just once, but more than once, I think are important principles that we need to think about, as we sort of go through this. The standards and interoperability framework is intended to help us with the how right now. And I think, when it comes to things like recognizing something as a standard, for example, we need to figure out who needs to do that. There, are you know, there are international standards organizations such as ISO that we can turn to: IETF, OMG, HL-7, IHE.

I used to say that the wonderful thing about standards is there are so many to choose from. It's actually, the wonderful thing about standards development organizations is that there are so many to choose from. But one could imagine that a project like Direct, which has not focused on content, but has focused on transport, might engage a different standards development organization or process than one that would, say, address a highly constrained C32 or to be looking at some of the C62 or C83 specifications that have come out of HITSP. There would be a different organization that perhaps would have contributions there. I think we have to be cognizant, and I don't have the answer as to who will emerge to be the IETF. But I think we would do well to recognize the value of some of the principles that come from IETF: core, simple, foundational kinds of constructs that then serve as a building blocks that allow innovation to be driven on top of that.

John Halamka – Harvard Medical School – Chief Information Officer
Kevin?

Kevin Hutchinson – Prematics, Inc. – CEO
Doug, thanks for all the hard work, and Arien on the phone as well. You guys have gone through quite a bit in a very, very short time period. I think tying both the presentations together and the concern that I'm even having, which is the role of the standards committee and the acceptance of the recommendations that we're making as part of these projects, is simply a timeline issue, I think. We have the NHIN Direct, which is on a very short timeline to prove a particular thing and drive momentum. We have the S&I framework, which is more long term. We have the policy committee and the standards committee that's focused on meaningful use requirements, some of those being at the data level.

More and more, as we move into stage two and stage three, we're going to be focused on more of the exchange level. We did that a little bit in stage one, but I would encourage ONC to step back briefly and think through the processes by which these are starting to emerge into a single approach because we have NHIN Direct. We have the S&I. We have the policy committee and the standard committee, and we're all moving in the same direction towards the interoperability of patient information.

I've been a pretty vocal person on the term EHR. We always throw it around like it's bottled water that you take off the shelf, and here's your EHR. And really, EHR is about the exchange of patient information and the accessibility of that information. And we're moving quickly in that direction, as we get to stage

two and stage three. And it's not – in my mind right now, it's not clear the processes, and you're doing a great job of teeing this conversation up because I think you see the same thing in the direction that it's going of, is this the right process by which to lay out the S&I framework. I think the answer to that question is, how is that tied into the stage two and stage three work that's being done by the policy committee and the standards committee because this is verging very, very quickly. I'd say, in the next couple of months, we need to understand what our priority is going to be starting into 2011 and how that relates to these tasks.

I think you've got a good, broad participation of an audience, both at the policy committee level and at the standards committee level that we can utilize for those things. But I would hate for us to keep bumping up against what's going on in with the NHIN Direct and S&I and standards and policy because it is all about exchange of information.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
It's one of the reasons why on this particular slide with priorities one, two, three, and four. I had examples there before, I took them all out because I didn't want the conversation to be about, well, why is the one on priority number two happening after priority number one because I know you guys, because ultimately this is really about enabling those things to happen. And how we can do that in the most efficient and expeditious way. If, at the end of the day, we run through one of these priority initiatives, and we get it done in nine months, or we get it done in a year, but we've only got one implementation, and there's still more that we need to learn, then we really need to maybe step back and say is this ready for prime time? Are there things?

Or if we go through this, and what we've done is we've aggregated a series of other things that people have – there's been sort of a pent up energy on, and now we've got a lot of momentum there, and we see that this is a good thing to have incorporated, then we can also take a look at that as well. But I think I want our standards and interoperability framework to not be the focus, but to be in service to these higher-level objectives that we've got, and to be cognizant of what those goals are. Like I said, the success of the S&I framework should be measured in terms of its ability to contribute to those larger goals because I can construct any sort of metrics that will make everything green, but that's not the goal with all of this.

John Halamka – Harvard Medical School – Chief Information Officer
Go ahead, Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Just a couple of quick comments. One, I really applaud Doug for picking a really tangible goal like reducing the cost of lab interfaces by 90%. Although, as you try to think how to measure that, you could maybe find a little more tangible way to phrase it. And I hope that he will structure the process so that he can tune it up, working on one tangible goal rather than 100 in parallel.

Second, the issue about the IETF or its equivalent, everyone should be aware that the last interaction the healthcare system had with the EITF was pretty much a disaster. There was an attempt to get EDI over the Internet standards. There are … there were implementations, and they could never get on the agenda to get it approved because it didn't have the necessary weight in view of EITF, which was much more concerned about a highly scaleable infrastructure.

And, third, that there are no content standards that I'm aware of under IETF other than content, as it relates to the operation of the protocols that EITF maintains. So while I think it's good to have the notional idea of, we need an EITF, I would hate to see us say we need the IETF.

John Halamka – Harvard Medical School – Chief Information Officer
Great. Thanks very much, Wes. Cris Ross?

Cris Ross – LabHub – CIO
Doug, part of what I'm trying to understand again is some practical kind of things, and I'm either going to annoy the heck out of you again, like I did last time, but we had a hearing, and I asked the question of what is this going to produce. Is ONC in the business of developing software? Is that software going to go through a standards organization and so on? After the hearing we had in September, one of the contractors working on this project wrote an article that was in government health IT news that said, "The use of national information exchange model to promote health information exchange represents a major shift of direction by policymakers working on expediting use of the national health information network."

I sent that to you and some other folks, and I was really interested in understanding what the context of that was about. I'm either the dumbest guy in the room, which is often true, or there's something going on here that I just don't understand it. I really don't understand whether ONC, for instance, if we're going to develop a lab interface, is that going to be required that labs use? I think it might be a great idea, but are labs going to be required to do it? What standards process will it go through to determine if it meets meaningful use standards and other things? I literally don't understand. So I hear the music, and I want to be inspired by it, but I don't understand the words.

John Halamka – Harvard Medical School – Chief Information Officer
Do you want to start? I'll make a comment as well.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I guess one question I would direct actually would be to Arien and the Direct project because, if you think about each one of those priorities or the initiatives, substitute priority one and just put in the Direct project. The Direct project had a community of folks that came to the table. They established some pretty clear objectives about what it was that they wanted to accomplish. They did it out there in the open and in a transparent way.

There are still issues that we need to resolve about this is a specification that was developed, and I'm always careful to say it's not the NHIN Direct standards because it hasn't been through a standards development process. It hasn't been acknowledged as a standard to this committee. It's a specification. To Cris' point, if you want to be able to adopt something as a standard, but you need to have something out there that people can test and implement and look at, you've got to get the specification first, and then you can start talking about the standard.

And so if you think about the NHIN Direct project, and that's the focus, that's the way in which we would achieve whatever the priorities that come from the meaningful use, the policy committee, from the standards committee about the stuff that we're supposed to work on, the standards and interoperability framework is intended to coordinate and support that work. And so to try to explain the standards and interoperability framework, I think misses the point, and I'm happy to sit down and explain to it in more detail. But the goal of the standards and interoperability framework is to support those other initiatives.

Arien Malec – RelayHealth – VP, Product Management
Doug, would you mind if I had a try at it to see if I could…?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Can you help me out here?

Arien Malec – RelayHealth – VP, Product Management
Yes. If we take, and we're not saying this is one of the first initiatives, but if we take Doug's goal of reducing the cost of an ambulatory lab interface by an order of magnitude, then part of what needs to be done is assess what are the current obstacles. What's the current cost chain, value chain for a lab interface? What's the current cost of that value chain? What are the current obstacles to achieving that value chain? And where do we have interoperability issues? And how can we attack those interoperability issues in a focused way?

When we come through the process, there will be, you know, the goal of the S&I framework is to make sure that the endpoint of that process has, for example, lab content, lab vocabulary standards that then map to later quality improvements, C32 or continuity of care or CCD content standards that you can use the same standards that are being developed or the same specifications that are being developed for solving a lab interface problem in other contexts. The goal of the S&I framework is to achieve value across multiple iterations and make sure that we have consistency across those iterations. In terms of what would happen in that first project, there may be some aspects of it that will go back to a standards development organization for endorsement.

There may be some aspects of it that get incorporated into regulation. Some of this may just be using the other policy tools at the standards committee's disposal and at ONC's disposal to make sure that there's alignment around this way of operating that works with RECs, with state STEs, with beacon, with federal partners to make sure that we're aligning industry using a variety of tools to solve that particular concrete problem. So I'm wondering if that helps conceptualize what it is that the S&I framework is and what the individual projects are intended at doing.

John Halamka – Harvard Medical School – Chief Information Officer
Let me just add a few thoughts, which is, having done this now for about seven years, what I've seen is we have many of these pieces and parts already in the ecosystem, but it's been a waterfall effect. So, as you say, I'm green. Here you go. I'm green. Here you go. Before you know it, you get to the end of the chain, and you haven't created value.

And so what the attempt here is to try to now, instead of having a waterfall, it's a set of parallel processes to try to get to measured value at the end. As well, I don't know that we've had a good way of dealing with the creation of new standards that haven't existed before that require multiple bits of domain expertise. As we've sort of said in this group, it's there's a particular, I want to focus just on this summary document, you've got processes in SDO to do that. If you have content vocabulary and transmission, you need to get to the end with all of that fully integrated across multiple SDOs. There hasn't been a well-defined process to do that, so this an attempt to address that.

You also asked, how do you get an adoption and does ONC really have an effector arm to get this done with the labs? The answer is, it probably doesn't. That is, ONC has got wonderful capabilities, but it can achieve meaningful use among provider organizations, and we hope the provider organizations demand of the commercial laboratory certain functionality. But I don't know that David Blumenthal's job description entails telling the labs what they can and cannot do.

One hopes, again, we get the community together. We solve the problem using all these tools that you've done in a parallel fashion, and create value the community of users then demands all of the suppliers to adopt so that the ecosystem can then function best. That's sort of the way I think about this, but more to come, more to be discussed. Now Jamie, and then Walter, and then we are at time for public comment.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great. Thank you. I'm glad we're staying on this slide because I wanted to ask about basically the process and methodology for determining the priorities. I know you said that you get input from the policy committee and standards committee and then how the priorities will emerge, but it seems to me that there ought to be some defined structured methodology that considers inputs and has evaluation criteria and evidence and a bunch of things behind the determination of the priorities. And that kind of feeds into the next, which is really my main point and question for you is about the timing of these different, simultaneous threads of activity because you've got them set at two months each. I realize that's probably just an arbitrary example for illustrative purposes. But I think that basically simple problems can move more quickly than complex problems. Not every problem is the same in terms of timing and fits the same mold.

In particular, one of the things I think we have learned from the Internet is that multiple orders of magnitude of difference and complexity makes comparisons break down. And so I think that, case in point, the NHIN Direct work, which I want to acknowledge the good work that was done and that continues to be done there. But either picking or unpicking one transport spec from a small list of transport specs is at least two orders of magnitude, if not more, less complex than designing a legally compliant clinical lab interface for results of tests on human subjects. These are different, multiple orders of magnitude in complexity. And so I want to say that in terms of the prioritization process, as well as the scheduling, it seems to me that having this fixed timeframe where we're going to start a new one every two months may in fact not fit if there's such dramatic differences of orders of magnitude in complexity. Since the different priorities may have different orders of magnitude of complexity, how do you anticipate dealing with that and just the basic fact that more complex things can take a lot longer?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
A couple of comments: First, the priorities that we have within the office and the things that we need to support within the standards and interoperability framework really are around meaningful use and the presidential initiatives around the virtual lifetime electronic record of the VLER project. And so those two things are things that we've got. We have a mandate to try to make successful and to support.

There are likely going to be important things to work on that don't fit into either of those two buckets, and it's one of the reasons why tools and services and sort of the support, I think, is important. Ultimately it would be nice if people could interact with this in a lot of different ways. They could say we have an initiative that has gone through a process of prioritization, and we will devote real resources to it because it's on the meaningful use path, or it's on the VLER path.

There may be other situations where someone says, listen, I don't want to consume any of your resources, but I like the approach. And I'd like to kind of follow and use your tools, and I'd like to use some of the other pieces. There needs to be a way that people may be able to engage if they're not part of those two priorities.

Third is, somebody may say, listen; we don't even need to use your tools and infrastructure, but if you've got a kind of standard way in which you express use cases, or the way in which you create these IEPD or these UML diagrams, there may be a way that I can just work on this separately, knowing that they may be able to merge together. And so I think there are different levels and different ways of engaging, and I think each one of those probably requires a different kind of prioritization or mechanism.

We obviously have specific charge to make sure that we support meaningful use through its stages in the VLER project. Then beyond that, I think we may identify something that says we believe that this is foundational, and we're not there yet, and we need to spend some time. Even though it's not part of those processes, we want to support that. I don't have at this point what that governance structure should look like, and I think that that's something that we need to have kind of further discussions about. I know that the principles about making sure that we do this transparently and that we do this out there in the open, I think, will be helpful, as we think about that and making sure that we stay focused on meaningful use and the VLER project.

The other thing you mentioned was about complexity, and you're right. There are a lot of complex problems out there, but oftentimes we solve complex problems by breaking it down into smaller chunks that we can solve. If you've got a big math equation or something like that, I mean, you typically take it, and you don't try to solve it all at once, but you break it down, and you factor it out, and you figure out how to solve different pieces. And then you reassemble that solution that need to go forward with.

And so, I think that's something that we need to consider. If we've got a complex problem, we say it's going to take us five years to solve this, and we begin work. And then five years later, we have the

solution. Things may be very different. And I think it's important for us to be able to think how we can take complex problems and break them down into manageable chunks that we can take care of.

And I think the last comment is that we the thing that I keep saying this, and it goes back to what John was saying about everybody being green but not producing value. It seems to me that that has to be a really sort of central focus, and it may be that these smaller projects will have only incremental value. One of the concerns is that you end up in a local minima. You're not really sort of maximized, but you've sort of got a local optimization, and you haven't gotten to that global optimization. And there's a risk, I think, with this, particularly with all the complexity and all the pieces.

But I'm hopeful that if we have a way that we can, again, going back to the comments about ultra large-scale systems. If we have a process that allows us not to get it right the first time, and to go back, and to fix it and modify, because ultra large-scale systems basically say you aren't going to be – I like to use the analogy that we talk about architecture, about building buildings, and that works really well if you're building a piece of software because you can say, here are where the floors are and where the exists should be and where the HVAC should be and all those other things. But no one would profess to try to design a city using architectural principles that says we need to have a building right at this location, and it needs to look exactly like this.

What we're doing here really is city planning, not architecture. I have read that book, all 38 of the beginning pages because I think it's critical. I think I have two copies of it actually, one that I give out. But the idea is that within this framework, we may be able to set up the priorities about how we're supposed to solve particular problems and try to use some of the coordinating mechanisms about putting these concepts in databases and reusing them to figure out what our building codes should be and figuring out what our principles should be and trying to reuse these things, in a sense, to do the city planning that needs to happen.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Let me play back part of what I think I heard and make sure I got it right. Given that you're going to have a set of problems to be prioritized, some of which are complex, some of which are simple, some of which are immediate. The idea in terms of complexity is to try to break them all down to chunks of roughly equivalent complexity into smaller chunks so that they can be sort of regularized in terms of schedule and process. Is that a fair characterization?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think I want to be able to – I mean, for one thing is the S&I framework, we've got two years basically from the ARRA stimulus money that we need to be able to leverage, so these are going to be things that I need to get the tools and the infrastructure and all those things built to help support this. I think we do need to break down the pieces. It's hard for me to be able to manage something that's got a complex goal at the end, and I don't know whether we're on the way to solving that problem until the end. We need to make sure that the pieces are being solved as we go.

And so even something that simple like laboratory exchange, and I'm not saying that – it's one of the simpler ones, but we need laboratory. We need compendiums. We need standards for vocabularies. We need value sets. We need – there are a whole bunch of pieces that have to fit into that.

I just think that, as we go forward too, as we get more and more complexity in the process, if we can capture what others have done before and move it forward, and that's kind of what this harmonization piece is supposed to do, maybe we can tackle some more complicated problems because we can build on the work that's gone on before and help support that. But I think, ultimately, we have to break it down into manageable chunks that you can make sure that we're on track and that we're not getting ourselves in weird directions, and that I can make sure that all the folks that are working on this are also moving in the right direction to get us there.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks. Jim, related?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Yes. Just a note on ultra large systems and a number of the other topics we keep banging up against, parsimony, what does it take to control the complex open system. There is a decades long set of science and methodology around complex open systems, Rasmussen and Vasintae, that I think would inform what we're trying to do and is much more real world and much more carefully thought out than the ultra large systems things.

John Halamka – Harvard Medical School – Chief Information Officer
Walter?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I think my concern really with this is the organizing principle itself. I think focusing on solving problems rather than adding value is, I think, probably a wrong way of looking at this. If you look at the organizing principle itself, it gives the impression that this is a reactive framework whereby there might be a problem raised by someone, and that will be brought into this process by someone else, and it will be addressed through the process by addressing one or two elements. I think my suggestion would be on that regard that if you really want to set an organizing principle that that'd be adding value rather than solving problems. That would be my first comment.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think that's a great suggestion. I just didn't want to use the word use case.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
No. I didn't use it either.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I wanted to, because I think that has other kinds of connotations.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Sure.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Adding value, actually, I think, puts a positive spin on it, which I think is….

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Well, it's the ultimate goal, but the second comment is a little more substantive too, I guess, is in this slide. When you look at this slide, this gives the impression that priority one has only to do with use case of element and implementation specifications. Priority three has nothing to do with use case development, but only focuses on harmonization and then jumps all the way down to certification. Yet there is a little arrow that connects all the bottom boxes, and so it gives the assumption or has always been maybe the wrong assumption, but it was an assumption that all these boxes at the bottom were sequential and connected and preconditions of the previous one, to be redundant.

In other words, if you are going to be developing implementation specs, there has to be some harmonization. If you're going to do harmonization, there has to be a use case. And so this is breaking the mold perhaps of the assumption that maybe many of us had about the sequencing and how any of these priorities will come in and we'll have to start at the use case steps to complete the process.

John Halamka – Harvard Medical School – Chief Information Officer
I think the issue is it's a limitation of two dimensionality of the slide.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes. It's a PowerPoint limitation. I struggle sometimes to sort of express how. If I put all of the slides, all of the connections there, it would be a mass of arrows because that's how we have to solve the problem.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes, but I just want to be clear whether the boxes at the bottom are sequential and preconditions across all of the priorities.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
No. I have another slide that uses more of a kind of a model or an agile approach that has sort of hills and valleys as to where these activities occur. In general, use case and functional requirements goes through the whole project. There's a bump in the beginning, but it goes through the whole thing. And as soon as you get to certification and testing, there's a bump at the beginning. There's a bump in the middle. There's a bump at the end.

I have that slide. I didn't present that one here, but when you think about this, the point to take away from this is that the approach is not to make it about the sequential nature of the S&I framework, but that the teams that support all of those activities has to be team members on those priorities, and they have to be available throughout the continuum so that they are there to make sure that the testing and the certification. I presented this before, and we've talked about how NIST, which is going to help us with certification and testing, has to be involved throughout the whole process. It's just a matter of we lose, for the sea of arrows, we'll lose the representation. This was really just more illustrative to get the conversation started.

John Halamka – Harvard Medical School – Chief Information Officer
Judy, with that, I think we want to open it up to our public comment period.

Judy Sparrow – Office of the National Coordinator – Executive Director
Right. Yes. We would like to invite anybody in the audience who would like to make a comment, please queue up to the microphone the table. And if you're on the telephone, just push star, one. And if you're on your computer, you'll need to dial – anyway, the gentlemen at the table, if you'd state your name, your organization, and your comments are limited to three minutes.

John Feikema – VisionShare – President
Sure, and I won't take that long. I'm John Feikema, president of VisionShare, and a member of one of the workgroups within the NHIN Direct project, the best practices one. I just wanted to say a couple of notes just to expand on one of the things that Arien offered. I think that one of the things that's elegant about the NHIN Direct project is that it introduced and formalized the notion of a HISP as an option, not as a requirement.

I remember David McCallie talking about how we wanted to be able to, end user to end user or physician-to-physician, being able to talk. But introducing the element of a service provider that can help add value in that chain, whether they open the envelope or not, but add value is important. Especially one of the things that we're looking at, for example, is exposing REST services as an edge connector so that those communities that can deploy REST effectively can use that without needing to worry about what the backbone protocol is. So it's another way to extend that metaphor farther.

Now we realize that there are some normal limitations associated with REST, specifically security, and one of the ways we've addressed that is by requiring digital certificates all the way through the process so that you don't have that. And the last thing I wanted to note on that one is that, yes, certificate distribution is hard. It's not undoable by any means. We've issued over 16,000 of them across the country. The hard part is exactly the part that Marc mentioned, which is the policy behind that and having uniform policies so that people know what certificates they can trust, who they'd been issued by, and not only who they'd been issued by, but under what circumstances they'd been issued by is important.

That's one of the key things that we're addressing in the best practices workgroup within Direct is what are the policies for these trust anchors going to be? Under what circumstances can you know who to trust and who not to trust? Dixie, I think that'll help you understanding who the players are and what their role is.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Richard Singerman?

Richard Singerman – BioQuest – President
Dr. Richard Singerman. I'm the chief innovation officer and cofounder for TrustNet MD. We're a social media company for driving hospital physician alignment. When I was in an AHRQ conference, this comment is more about timing, and I was just speaking to Liz Johnson as she went out. At an AHRQ conference about a month ago stated that about 40% of Americans don't have one paid sick leave day, and yet it's October 27th, and we're already talking about kind of this holiday mindset and things kind of slowing down and stuff happening maybe in mid January.

Obviously there's a very pressing timeframe here, and this committee has gotten great work done, and I'd hate to already think that we're basically almost going to be on hiatus for two months. Things will be happening virtually, but I mentioned to Ms. Johnson, those hearings that she's talking about are about the implementation workgroup and the actual real world experiences, which are so valuable to know, could take place, especially virtually, in mid December, which would then inform mid January for the meaningful use work for Dr. Tang. And she mentioned, definitely mention that to this group, so that's still basically six or seven weeks ago, and I think it's achievable. Just on that note, the excitement that's gone on up to this point, being a cofounder of a young company, the holiday mind spirit is great, and we all want to enjoy the holidays, but we don't want to really lower the bar for the next two months because, like I said, 40% of us don't have even one paid sick leave, and I think it's incumbent upon us to remember those folks, as time really is of the essence. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer
I can promise no rest for this group.

Judy Sparrow – Office of the National Coordinator – Executive Director
That's right, John. Robin?

Robin Raiford – Eclipsys – Director of Government Initiatives
Robin Raiford, executive director of federal affairs at Allscripts. I just wanted to address a couple of comments that Jim Walker had. Really, I guess I'll need to send an e-mail to Liz Johnson because it's a recommendation for the groups in January whenever they occur about the situation where organizations are now coming to realize, I have to have a complete EHR that's certified. And for everyone to be aware, just for the public record, to check the ONC FAQ documents that are out there, specifically question number 14 and question number 16 that's answered that basically says, when you lay down that floor, if there are six pieces to that floor that got certified, you're not allowed to substitute 6 pieces of yellow tile with one piece of blue tile. To use Doug's term, your thousand blooms blooming or whatever, that you can't substitute a blue tile for a yellow tile. You can pout it on top of the yellow tile, but you can't substitute that tile. And questions 14 and 16 address that.

Now as people come out of denial that I have to have a complete EHR and I didn't substitute anything, I have to self-certify because I now cannot use the vendor certification because I don't have two pieces of that tile that are there. And I would just recommend that in that scheme of things that go forward, that people consider that situation because I think it's greatly going to affect. I went to an organization last week that is doing one million CPOE orders a month, one million a month that is now at risk for not being able to do 2011 because they didn't realize they had to have meds reconciliation in place because they

thought they could defer that until stage two, not just defer the reporting of it, that they needed a complete EHR. I think there's that kind of adjustment thing going on.

And a second thought I had was the meaningful use workgroup, just as a nurse, I want to come forward and say it is scary to listen to those discussions of meds administration, as well as nursing care plans without a nurse on that committee. So if maybe Liz or Judy could be loaned to that committee, it is pretty scary to hear that going on, albeit wonderful national leaders, that really is a huge nursing domain to jump into that space without a nurse on the committee.

Judy Sparrow – Office of the National Coordinator – Executive Director
Great. Thanks, Robin, and we did add a nurse, by the way. I think we have one comment on the telephone.

Coordinator
Our next comment is from Keith Boone with GE Healthcare.

Keith Boone – GE Healthcare – Standards Architect
This is Keith Boone with GE Healthcare. The one concern I have about how the standards and interoperability framework plays out goes back to understanding the value that we're actually asking to develop and making sure that what actually gets prioritized to be worked on is really of value. I want to see another Katrina use case where we're trying to deal with something that really isn't implementable. And I think the other piece of that that we need to recognize is, as others had pointed out, not everything works on the same schedule, and when you try to put these things on a particular schedule ….

Judy Sparrow – Office of the National Coordinator – Executive Director
I think we lost you, Keith.

John Halamka – Harvard Medical School – Chief Information Officer
But the point well taken about the difference in schedule and the need for value, absolutely.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you for all the public comments. Back to Dr. Halamka.

John Halamka – Harvard Medical School – Chief Information Officer
Well, a rich discussion today, and those virtual meetings will be very fruitful, I promise, so we will keep the momentum going over the course of November and December. I certainly hope you folks have safe travels today, and look forward to our next conversation. Thanks for attending.

Public Comment Received During the Meeting

1. SMTP for direct does not seem to contemplate that "pull" needs to follow "push". Isn't this a much bigger issue than how many Wiki edits there are?

4. There was some talk about PHINMS. Why was that not chosen for Direct? Would not that have saved much gov money?

5. With regards to the xml and EDI error in the FR; how shall EPs, EHs, and HIT Coordinators move forward with implementation as it applies to early adopters and A/I/U? Thank you.